

Multaq: August 2011 Update: Another Liver Failure Case Report Article In Medical Journal

New Sanofi "Dear Doctor" Letter: Label Change Regarding Heart-Related Side Effects Coming Soon

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 19, 2011; see <http://bit.ly/r6P47J>)

This August 2011 update on Multaq (dronedarone) covers both liver injury and cardiovascular side effects.

The medical journal *Circulation: Arrhythmia and Electrophysiology* published an article, "[Acute Liver Failure Associated With Dronedarone](#)", which described the case of a 70 year-old woman in Germany who developed a drug-induced liver injury associated with her Multaq use. From the Introduction section of that article:

A 70-year-old woman was initially referred to a community hospital for progressive fatigue and hyperbilirubinemia for 2 weeks. Six months before admission, she was started on [Multaq(dronedarone)] for atrial fibrillation.... She did not smoke, drink alcohol, or use illicit drugs....

On the basis of the timing of jaundice in relation to dronedarone exposure and the absence of any other identifiable cause, she was diagnosed with dronedarone-induced acute liver failure. Liver function tests did not improve with high-dose steroid therapy. On the 9th day of admission, altered mental status and beginning of hepatic encephalopathy was noted.

She was therefore transferred to the university hospital for liver transplantation.

In January 2011 it was announced that Sanofi-Aventis was sending a "[Dear Doctor](#)" letter [warning that Multaq had been associated with liver failure](#).

Now, [in August 2011 Sanofi sent another Multaq "Dear Doctor" letter; this one was about cardiovascular side effects](#).

In more detail, the subject this August letter was the PALLAS (**P**ermanent **A**trial fibrillation outcome **S**tudy using Dronedarone on top of standard therapy) phase IIIb clinical trial and why it was terminated early.

The cardiovascular side effects -- cardiovascular death, stroke, and cardiovascular hospitalization, primarily heart failure hospitalizations -- which resulted in the PALLAS study being discontinued [first got the attention of drug safety regulators in July 2011](#).

We will continue to monitor the safety profile of Multaq, both the liver injury and the various heart-related problems, going forward.

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>