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

Liver Toxicity And Cardiac Side Effects Cause Dr. Steven Nissen To Express "concerns about the safety, efficacy and tolerability of dronedarone"

(Posted by Tom Lamb at www.DrugInjuryWatch.com on January 14, 2011; see http://bit.ly/ejOcEX)

On January 13, 2011 reporter Larry Husten posted on Cardiobrief.org this article, "Sanofi-Aventis To Inform Doctors About Liver Transplants in 2 Patients Taking Multaq (Dronedarone)", which broke the news that Sanofi-Aventis' atrial fibrillation heart drug Multaq has been associated with liver failure and hepatic necrosis:

> Sanofi-Aventis is about to send a "Dear Doctor" letter to physicians informing them of two cases of fulminant hepatic failure/necrosis resulting in liver transplanation in two patients taking Multaq (dronedarone), CardioBrief has learned. The two patients were women in their 70′s with no other apparent causes of liver injury or known elevations of liver function tests (LFTs) prior to the acute liver failure. Liver failure developed after the women were taking dronedarone for four to six months.

On January 14, 2011 the FDA issued "Drug Information Update - Safety Communication: Severe liver injury associated with the use of dronedarone (marketed as Multaq)" which included these details from the Data Summary section:

> FDA has received several case reports of hepatocellular liver injury and hepatic failure in patients treated with dronedarone, including two post-marketing reports of acute hepatic failure requiring transplantation. Because these reactions are reported voluntarily from a treatment population of unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
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> The two cases of acute hepatic failure requiring transplantation occurred at 4.5 and 6 months after initiation of dronedarone in patients with previously normal hepatic serum enzymes. Both patients were female and approximately 70 years of age.... In both cases, the explanted liver showed evidence of extensive hepatocellular necrosis.

That same day, January 14, Larry Husten posted this Cardiobrief.org article, "FDA Warns About Severe Liver Injury Associated with Multaq (Dronedarone)", which included the impressions of Dr. Steven Nissen, a leading cardiologist:

> Steve Nissen provided the following comment to CardioExchange about Multaq:
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> > I have significant concerns about the safety, efficacy and tolerability of dronedarone. Although liver toxicity was not anticipated, other safety issues have been apparent even prior to launch. The increased risk of death in heart failure patients represented a particularly concerning finding in pre-approval studies. The drug is substantially less efficacious compared with amiodarone and the GI tolerability is poor. Despite these warning signs, the drug has been aggressively promoted, often through industry-sponsored CME offered by professional medical societies. Over-promotion of a risky drug during its initial launch period has been a historically important harbinger of serious safety concerns. Dronedarone may be headed for trouble.

As for the heart problems alluded to by Dr. Nissen, earlier in 2010 the FDA had listed "Dronedarone hydrochloride (Multaq)" twice for possible heart-related side effects:

- "Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) between January – March 2010" -- for congestive heart failure (CHF); and,
- "Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS) between April - June 2010" -- for Torsade de Pointes.

Moving across the Atlantic to Europe, according to a January 14, 2011 article, "FDA alert: Dronedarone and severe liver injury", published online by *heartwire*:

> EMA spokesperson Monika Benstetter told heartwire that the EMA has received the data on the liver injury cases [involving Multaq (dronedarone)] and that the issue has been placed on the agenda for next week's monthly meeting of the Committee for Medicinal Products for Human Use (CHMP).

As always, we encourage you to submit a Comment if you have additional information or insight about this emerging drug safety issue concerning Multaq and liver failure, or know of someone who developed a possible drug-induced liver injury while using 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