Diet Drug Meridia Has Possible Cardiovascular Risks, Including Stroke, Heart Attack, And Cardiac Death

FDA Early Communication About Meridia (Sibutramine) Side Effects Issued by Agency In November 2009

(Posted by Tom Lamb at www.DrugInjuryWatch.com on November 30, 2009; see http://bit.ly/80EItr)

On November 20, 2009 the FDA issued an "Early Communication about an Ongoing Safety Review of Meridia (sibutramine hydrochloride)" to let patients and their doctors know about a possible increased risk for adverse cardiovascular events associated with the obesity drug Meridia.

As background, Meridia was approved by FDA in 1997 for the management of obesity, including weight loss and maintenance of weight loss, in conjunction with a reduced calorie diet. Meridia is marketed by Abbott Laboratories in the U.S.

A November 21, 2009 article, "Early Data Link Diet Drug to MI, Stroke, and Cardiac Death", published online by *MedPage Today*, provides a good summary of the basis for this Meridia safety alert:

> Preliminary analysis of data from a placebo-controlled study of sibutramine (Meridia) suggested an excess risk of cardiovascular events including myocardial infarction and cardiac death among patients taking the diet drug, according to the FDA.
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> The findings come from a trial of 10,000 high-risk patients who were randomized to sibutramine or placebo. The FDA said there was a 1% absolute difference in the rate of heart attack, stroke, resuscitated cardiac arrest, or death with 11% of the sibutramine patients reaching that endpoint versus 10% of the placebo patients.
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> The difference, while small, "is higher than expected, suggesting that sibutramine is associated with an increased cardiovascular risk in the study population," the FDA said....
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> The findings come from the SCOUT trial (Sibutramine Cardiovascular Morbidity/Mortality Outcomes in Overweight or Obese Subjects at Risk of a Cardiovascular Event) which had a combined primary endpoint of heart attack, stroke, resuscitated cardiac arrest, or death.
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> The study, begun in 2002, was conducted as part of a postapproval agreement with the agency that oversees drug approvals for the European Union.

We last wrote about cardiovascular side effects being associated with Meridia use back in October 2007, when Health Canada provided an update on reports of suspected Meridia adverse reactions.

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.
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