Should Meridia Remain On Market? FDA Says "Yes" (For Now At Least), European Drug Regulators Say "No"

Difference Of Opinion Suggests There Could Be A Possible Meridia Recall In U.S. Before The FDA Holds Its Public Advisory Meeting In September 2010

(Posted by Tom Lamb at www.DrugInjuryWatch.com on January 25, 2010; see http://bit.ly/5f7a2w)

The beginning of a January 23, 2010 newspaper article, "Heart Patients Warned Against Using Meridia, an Anti-Obesity Drug" -- by Natasha Singer and Andrew Pollock for *The New York Times* (*NYT*) -- frames the issue:

> European and American drug regulators had two starkly different reactions this week to data on an obesity drug. The raw data from the study indicated that people with certain health problems who took the prescription diet drug Meridia had more heart attacks, strokes and other cardiovascular problems than people getting a placebo.
>
> On Thursday, the European Medicines Agency advised doctors and pharmacists to stop prescribing and dispensing European equivalents of Meridia. The Food and Drug Administration, looking at the same study data on Thursday, took a less forceful step and asked Abbott Laboratories, the maker of Meridia, to put a stronger warning on its label.

This January 23 *NYT* article also provided a glimpse of how the FDA might proceed as regards the fate of Meridia in the U.S.:

> ... the F.D.A. said it planned to wait for the company's complete report on the study, due in March, before considering further action on the drug. An advisory panel of medical experts is to review the results of the study in a public meeting, most likely in September, an agency spokeswoman wrote in an e-mail message to a reporter.

So how did these respective drug regulators in Europe and the U.S. come to such different opinions about Meridia when apparently looking at the same efficacy and safety data?

Perhaps the answer can be found in, or between the lines of, one of the several documents issued in Europe last week about Meridia (sibutramine) -- which is sold as Reductil, Reduxade, Zelium, and various other tradenames in the European Union.

To start, from the so-called Dear Doctor letter which was issued on January 21, 2010 (available by using the link found at end of an MHRA web page titled "Sibutramine: Suspension of marketing authorisation as risks outweigh benefits"):

> Dear Healthcare Professional,
>
> We are writing to inform you that the European Medicines Agency (EMA) has completed a review of the obesity medicine sibutramine (Reductil) on the basis of new safety information from a large clinical trial, the Sibutramine Cardiovascular OUTcomes (SCOUT) study. The review has found that the cardiovascular risks of sibutramine outweigh its benefits. The EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended suspension of the marketing authorisation for this medicine across the European Union....
>
> Although most of the patients enrolled within SCOUT are contraindicated from being treated with sibutramine under normal conditions of use, the Committee considered the cardiovascular risk to be relevant to normal clinical use because it is not always possible to identify underlying cardiovascular disease in patients who are obese or overweight. Therefore further restrictions on the use of sibutramine would be unlikely to reduce the risk to an acceptable level.

Other recent documents about Meridia from the European drug regulators include:

1) December 18, 2009 press release: "European Medicines Agency updates on ongoing safety review of sibutramine -- Weight-loss medicine assessed over cardiovascular concerns";

2) January 21, 2010 press release: "European Medicines Agency recommends suspension of marketing authorisations for sibutramine -- Weight-loss medicine associated with increased risk of cardiovascular events to be removed from all markets in the European Union"; and,

3) "Questions and answers for recommendation to suspend sibutramine (Reductil) from the EU market".

Or, perhaps there is an explanation somewhere within the FDA's "Follow-Up to the November 2009 Early Communication about an Ongoing Safety Review of Sibutramine, Marketed as Meridia", issued on January 21, 2010.

Lastly, for those who want to dig deeper, you can read about the recent Meridia study, itself -- "A Long Term Study of Sibutramine and the Role of Obesity Management in Relation to Cardiovascular Disease in Overweight and Obese Patients. (SCOUT)" -- at the ClinicalTrials.gov web site.

What do you think? Did the FDA get it right or wrong as regards the issue of whether Meridia should remain on the market in the U.S.?

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