Will The FDA Follow The EMA And Order A Meridia Recall After Its September 2010 Advisory Committee Meeting

NEJM Editorial: There Should Be A Meridia Recall As The Risk Of Heart-Related Side Effects Is Greater Than Any Weight-Loss Benefit

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 10, 2010; see http://bit.ly/dzvsvP)

According to a recent medical article, "Effect of Sibutramine on Cardiovascular Outcomes in Overweight and Obese Subjects" (Abstract), published September 2, 2010 by the *New England Journal of Medicine* (*NEJM),* patients with preexisting cardiovascular conditions who were given the obesity drug Meridia (sibutramine) over a long term had an increased risk of nonfatal myocardial infarction (MI), or heart attack, and nonfatal stroke, but not an increased risk of cardiovascular death or of all-cause mortality.

These new findings came from the full results of "A Long-Term Study of Sibutramine and the Role of Obesity Management in Relation to Cardiovascular Disease in Overweight and Obese Patients" -- which is commonly referred to as the Sibutramine Cardiovascular Outcomes Trial (SCOUT). The September 2010 *NEJM* article referenced above was authored by the SCOUT investigators.

Previously, the preliminary results from the SCOUT trial were first released by the FDA in their "Early Communication about an Ongoing Safety Review of Meridia (sibutramine hydrochloride)", issued back in November 2009. That Early Communication was intended to let patients and their doctors know about a possible increased risk for adverse cardiovascular events associated with the obesity drug Meridia.

On September 15, 2010 an FDA Advisory Committee will meet to discuss the full results of this Sibutramine Cardiovascular Outcomes Trial (SCOUT).

As background, in January 2010 -- after having considered the preliminary results from the SCOUT trial -- the European Medicines Agency (EMA) advised doctors and pharmacists to stop prescribing and dispensing European equivalents of Meridia.

At about the same time the FDA, after looking at the same SCOUT study data, took a less forceful step and simply asked Abbott Laboratories, the maker of Meridia, to put a stronger warning on its label.

In more detail, in January 2010 the FDA issued its "Follow-Up to the November 2009 Early Communication about an Ongoing Safety Review of Sibutramine, Marketed as Meridia".

In relevant part, this January 2010 FDA document called for a stronger warning on the Meridia package insert, or label, which had warned against the use of Meridia by patients with cardiovascular disease (CVD). With the revision requested by the FDA, that CVD warning would become a "contraindication", *i.e.*, a higher level of warning, and would state that Meridia should not be used in patients with histories of:

- coronary artery disease, including MI and angina
- congestive heart failure
- arrhythmia
- stroke or transient ischemic attack
- peripheral arterial disease
- uncontrolled hypertension

Notably, the September 2, 2010 edition of the *NEJM* also had an accompanying Meridia editorial, "Sibutramine — Another Flawed Diet Pill" (first 100 words; subscription required for full text), by Dr. Gregory D. Curfman and colleagues, which disagreed with the conclusion reached by the SCOUT investigators, namely that no changes are needed as regards the current clinical use of Meridia, *i.e.*, limited to patients without preexisting cardiovascular disease (CVD).

In that September 2010 *NEJM* editorial Dr. Curfman and his colleagues write:

> The investigators' conclusion is based on a narrow interpretation of the SCOUT data, in which only the patients with preexisting cardiovascular disease had an increase in the risk of new cardiovascular events....
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> We surely need safe and effective medications to help overweight and obese patients lose weight and improve their long-term health. But given that sibutramine has minimal efficacy for weight loss, no apparent benefit for clinical outcomes, a worrisome cardiovascular risk profile, and a plausible mechanism to explain the cardiovascular risk, it is difficult to discern a credible rationale for keeping this medication on the market.

So will the FDA follow the EMA, now, and order a Meridia recall sometime after this September 15, 2010 Advisory Committee meeting, or not? Be assured we will be watching for this outcome and report it here.

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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