

[2006 Case Report Indicating That Xenical \(Orlistat\) May Cause Substantial Acute Liver Injury](#)

Medical Journal Letter To Editor Stated That Exact Mechanism Of Hepatotoxicity In Subject Patient Was Unknown

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 31, 2009, see <http://bit.ly/S3E6a>)

As we reported, [on August 24, 2009 the FDA issued its "Early Communication" notification](#) about an ongoing safety review of the obesity drugs Xenical (orlistat 120 mg) and Alli (orlistat 60 mg).

While that announcement by the FDA was the first time some people had heard about possible serious liver-related side effects caused by Xenical and Alli, this safety issue is not new.

In August 2006 *The American Journal of Medicine (AMJ)* published online a Letter to the Editor item titled ["Severe Hepatic Injury Caused by Orlistat"](#) which presented a then-recent case of acute hepatic injury in a 15-year old woman who was using Xenical.

From this August 2006 *AMJ* item:

A 15-year-old Thai woman without remarkable medical history had taken orlistat (120 mg three times daily) for 7 days because of concerns of obesity. One week later, the patient was admitted to an emergency hospital with abdominal pain, malaise, nausea, and diarrhea, and was transferred to our hospital the following day. She had no toxic habits and denied taking any other medications or herbal remedies.... The patient's serum aspartate aminotransferase and alanine aminotransferase levels were surprisingly high at 8269 IU/L and 9976 IU/L.... The results of screening for viral hepatitis (hepatitis A, B, C, and E virus; cytomegalovirus; Epstein-Barr virus) and autoimmune markers (antinuclear antibodies and antimitochondrial antibodies) were all negative. Abdominal ultrasound, computed tomography, and magnetic resonance imaging all showed normal findings. The patient was given vitamin K intravenously for 5 days, and liver function test results normalized within 1 month.

Based on these findings, the treating physicians arrived at these determinations:

- The exact mechanism of hepatotoxicity in our patient is unknown, although the presence of low-grade fever, eosinophilia, elevated immunoglobulin-E level, and cytopenia indicates an immunoallergic reaction.
- In addition, the temporal association between the institution of orlistat and the onset of hepatic abnormalities, the resolution of symptoms and the improvement of abnormal liver function test results after the drug was stopped, and the absence of alternative explanations strongly suggest that orlistat caused her liver injury.
- The Clinical Diagnostic Scale⁴ also has indicated a probable relationship between acute hepatotoxicity and orlistat, which is in agreement with our report indicating that orlistat may cause substantial acute liver injury. [footnote omitted]

We will be watching to see if there is an increase in the number of [MedWatch reports submitted to the FDA](#) concerning about Xenical or Alli and serious liver injury including liver failure due, perhaps, to media coverage of the FDA's announcement in late August 2009 about its ongoing safety review of Xenical and Alli.

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>