

## [Some Users Of Alli And Xenical Have Developed Serious Liver Injury Including Liver Failure](#)

### **FDA Early Communication Makes Clear That No Definite Association Between Liver Injury And Orlistat Has Been Established At This Time**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on August 24, 2009)

On May 22, 2009 we first reported that [the FDA is investigating the obesity drugs Xenical and Alli for a possible link with liver damage](#).

About three months later, on August 24, 2009, the FDA issued its "[Early Communication about an Ongoing Safety Review Orlistat \(marketed as Alli and Xenical\)](#)".

From this August 2009 Early Communication about Alli and Xenical:

Between 1999 and October 2008, 32 reports of serious liver injury, including 6 cases of liver failure, in patients using orlistat were submitted to FDA's Adverse Event Reporting System. Thirty of the 32 reports occurred outside the United States. The most commonly reported adverse events described in the 32 reports of serious liver injury were jaundice (yellowing of the skin or whites of the eyes), weakness, and abdominal pain. Hospitalization was reported in 27 of the 32 cases.

In addition to the 32 reported cases, this issue was discussed at the CDER Drug Safety Oversight Board in April 2009, and FDA is reviewing other data on suspected cases of liver injury submitted by the manufacturers of orlistat. FDA's analysis of these data is ongoing and no definite association between liver injury and orlistat has been established at this time.

We will continue to monitor and report on the safety profile of Alli and Xenical.

If you are aware of any cases of drug-induced hepatitis, liver injury, or liver failure involving the use of Xenical or Alli, please let us know by submitting a Comment, below, or you can [send me a private email](#).

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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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