Rheumatoid Arthritis Drug Arava Gets Increased Warning For Liver Injury In July 2010

The Bolded Warning About Severe Liver Problems Which Was Added In 2003 Is Replaced By "Black-Box" Warning

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 22, 2010; see http://bit.ly/bAkmGi)

On July 13, 2010 the FDA issued a MedWatch Alert about a new increased warning about the association between the rheumatoid arthritis drug Arava (leflunomide) and severe liver injury.

The basis for this new Arava "black-box" warning is explained in this July 2010 document, "FDA Drug Safety Communication: New boxed warning for severe liver injury with arthritis drug Arava (leflunomide)":

> In 2003, a bolded warning statement about the risk of severe liver injury and a recommendation to monitor liver function tests every 6 to 8 weeks were included in the professional prescribing information for leflunomide. In 2009, based on continued reports of severe liver injury, FDA conducted an updated review of severe liver injury and leflunomide and identified 49 cases, 36 which required hospitalization, reported between August 2002 and May 2009.
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> The estimated duration of leflunomide treatment before the occurrence of severe liver injury ranged from 9 days to 6 years, with the majority of patients developing severe liver injury within the first 6 to 12 months of treatment.
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> Of the 49 cases, there were 14 deaths. An additional five patients required a liver transplant and nine patients experienced a life-threatening event....

As background, from the FDA's "Leflunomide (marketed as Arava) Information" page:

> Arava (leflunomide) is indicated in adults for the treatment of active rheumatoid arthritis (RA):
>
> 1. to reduce signs and symptoms
> 2. to inhibit structural damage as evidenced by X-ray erosions and joint space narrowing
> 3. to improve physical function.

Returning to the July 2010 document, the FDA had this important advice for patients who are using Arava:

> Contact your healthcare professional if you develop itching, yellow eyes or skin, dark urine, loss of appetite, or light-colored stools. These may be signs of liver injury.

For physicians and others interested in knowing more about why a black-box warning abour severe liver injury was being added to the Arava label, the FDA has an audio podcast available: "FDA Drug Safety Podcast for Healthcare Professionals: New boxed warning for severe liver injury with arthritis drug Arava (leflunomide)" - mp3 (MP3 - 11276KB)

Our law firm is investigating possible Arava lawsuits for patients who were hospitalized for serious liver problems, ranging from drug-induced hepatitis to liver transplant, and for the families of patients who have died from liver failure after using Arava.

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