## Antibiotic Avelox Linked To Severe Liver Injury Side Effects, Again

## Will The FDA Be The Last To Insist On Increased Warning; In Fall 2007 Bayer Updated Its Avalox Label In Europe

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 23, 2010; see http://bit.ly/aLn5CR)

On March 22, 2010 Health Canada issued a press release, "<u>Updated Labelling for Antibiotic Avelox</u> (<u>Moxifloxacin</u>) Regarding Rare Risk of Severe Liver Injury Information <u>Update</u>", which informed doctors and patients about newly updated labeling information for Avelox in Canada that incorporates important safety information related to the rare risk of severe liver problems when using Avelox.

Symptoms of liver problems include:

- Abdominal pain;
- Loss of appetite;
- Yellowing of the skin and eyes;
- Severe itching;
- Dark urine; and,
- Pale-colored stools.

In its March 2010 press release about Avelox, Health Canada advised:

Patients who experience any of these symptoms are advised to stop taking Avelox and contact a health care professional immediately.

While this advisory from Health Canada about Avelox is important, it is far from new.

In an article which we posted to this site more than two years ago, "February 2008 'Dear Doctor' Letter About Avelox / Avalox Is Sent By Bayer In Europe", we reported that this letter from Bayer to doctors in Europe was intended to emphasize the addition of a warning about severe, possibly fatal liver injury to the package insert, or label, for Avalox (slightly different brand name for this antibiotic is used in the European Union) back in the fall of 2007.

We concluded our February 2008 article about this Avalox "Dear Doctor" letter that Bayer sent out only in Europe with this remark:

We will watch for any similar Avelox "Dear Doctor" letter from Bayer here in the U.S.

Two years later, we are still waiting and watching, here.

It is unclear thus far whether Bayer will notify doctors in Canada by letter about the Avelox label change concerning the risk of liver injury for patients using this apparently unsafe antibiotic.

Here's our "obvious" question to the FDA, now: Is the FDA looking at Avelox for serious side effects such as drug-induced hepatitis and liver failure, which seem to be unique to this antibiotic among the fluoroquinolones?

We would like to hear about what you know regarding this liver-related Avelox safety issue. As always, please share by leaving a Comment, below.

Attorney <u>Tom Lamb</u> 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