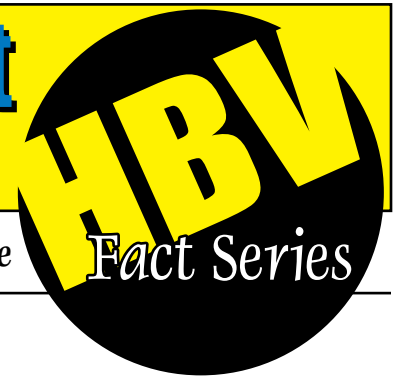


Hepatitis B Fact Sheet

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a series of fact sheets written by experts in the field of liver disease



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Hepatitis B: Reporting Drug Side Effects

Prior to the release of a new medication, clinical studies are conducted that 'test' a drug for safety, effectiveness and other important issues before marketing approval. Safety is given the highest priority when testing a new drug.

Nevertheless, sometimes drug side effects slip through the cracks, and the results can be life-threatening. The problem is that most clinical trials study the 'easiest' populations. Also, even though there are between 1,000-3,000 people being treated, no complete picture develops until the drug is released to the general public (with that condition).

In the *FDA Drug Safety Newsletter*, an overview of the FDA approved drug atomoxetine (brand name Strattera) was discussed. Atomoxetine was approved on November 26, 2002 as the first non-stimulant medication for the treatment of attention deficit hyperactivity disorder (ADHD) in children (ages 6 and above) and adults. In the period between 2002 and 2007 about 3.3 million people received a prescription of atomoxetine (about 64% were children 17 years or younger). Liver injury was only found after the drug was approved. In 2004, after 2 published reports, the FDA added a bolded warning about severe liver injury associated with the drug. Six additional reports of serious liver injury since 2004 were reported to the FDA, which prompted a revised product label that included stronger language in 2007.

The FDA also advised healthcare professionals and patients to be aware and report any further cases to the FDA's MedWatch. Between January 2005 and March 19, 2008 there have been six more events reported to the Adverse Events Reporting System (AERS). Based on these reports the

FDA is continuing to monitor the adverse events.

Again all of these events were AFTER the drug was FDA approved. This is important information to know and as providers and patients we must report any adverse events directly to the FDA.

In regards to hepatitis B, when telivudine was approved by the FDA for treatment of chronic HBV some physicians were prescribing it in combination with interferon (which had not been approved by the FDA). Reports started surfacing that patients taking the combination were developing peripheral neuropathy. As a result the FDA issued a change to the product packaging warning about the risk of peripheral neuropathy, recommending that the two products should not be taken together.



Reporting Drug Side Effects

To recap the clinical trial process:

- Pre-clinical trials are conducted basically in a test tube.
- Phase 1 trials are small studies (~20-80 people) that evaluate the safety, determine a safe dose and identify side effects. Phase 1 studies involve both healthy people (without the condition or disease) and patients with the condition for which the drug is intended.
- Phase II studies are larger studies (~100-300 patients) that continue to evaluate the safety and effectiveness of the drug in patients with the targeted condition. The majority of drugs that reach phase II studies are cancelled due to lack of effectiveness or safety concerns. Since more patients are using the experimental drug it will give a better picture of the safety and effectiveness.
- Phase III studies are large studies (~1,000-3,000 patients) that continue to evaluate safety and effectiveness and also compare the new drug to the stan-

dard of care. If a drug is found to be as effective as the current standard of care and if there are no extreme safety issues, the pharmaceutical company will apply to the FDA for marketing approval. Phase III studies have a much larger patient population and, as a result, will give a much better picture of the safety and effectiveness of the study drug.

- Phase IV or post-marketing studies are conducted to find out about treating sub-populations with the same condition that may not have been included in the original studies or for the treatment of a different condition.

**Reporting Adverse Events**

Report serious adverse events to FDA's MedWatch reporting system:

- by completing an online form at www.fda.gov/medwatch/report.htm,
- by faxing (1-800-FDA-0178),
- by mail using the pre-paid postage address form provided online (5600 Fishers Lane, Rockville, MD 20852-9787),
- by telephone (1-800-FDA-1088).

Source:

FDA Drug Safety Newsletter
www.fda.gov/cder/dsn/default.htm, Volume 2/number 1/2009

See also: "What the Heck is Hepatotoxicity?" by Lucinda K. Porter, *HCV Advocate*, June 2009.

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The information in this fact sheet is designed to help you understand and manage HBV and is not intended as medical advice. All persons with HBV should consult a medical practitioner for diagnosis and treatment of HBV.

For more information about hepatitis B, visit the following websites.
Hepatitis B Foundation: www.hepb.org • HIVandHepatitis.com

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