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

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HCSP FACT SHEET

•HCV TREATMENT: GENERAL INFORMATION•

Reporting Drug Side Effects

Written by: Alan Franciscus, Editor-in-Chief

Foreword

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

Nevertheless, sometimes drugs 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 in clinical trials, no complete picture develops until the drug is released to the general public to treat many more hundreds and thousands of patients with that condition.

The following is an example of how additional safety concerns are found when a drug is released into the general population:

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 to 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 assocated 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.

HCSP FACT SHEET

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Reporting Drug Side Effects

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. It is even more important now that the new HCV protease inhibitors have been approved and marketed so that we can learn about any severe or potentially life-threatening conditions that may only show up when more people take the medications.

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. If you look at HCV drugs in development you will find that the vast 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 standard 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:

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

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