June 2010: FDA Launches Its Postmarketing Drug Safety Evaluations Web Site

New FDA Site Will Include A Summary Analysis Of Recently Reported Adverse Events And Related Medical Articles

(Posted by Tom Lamb at www.DrugInjuryWatch.com on June 17, 2010; see http://bit.ly/ao8xtw)

In mid-June 2010 the FDA announced that it will be making safety evaluations of postmarket adverse events publicly available on a new web site, Postmarketing Drug Safety Evaluations, and will update the information posted there on a quarterly basis.

From the agency's June 15, 2010 press release, "FDA to Communicate Safety Monitoring Activities to Consumers and Health Care Professionals":

> Summaries of FDA safety analyses on recently approved products will now be periodically prepared and posted on FDA's website along with a brief discussion of the steps FDA is taking to address any identified safety issues.
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> Some side effects may not become apparent until after a medicine has been approved and becomes available to a larger, more diverse population than the patients who participated in clinical trials that supported approval. The new summaries provide a comprehensive look at safety data early in the product's post-approval life cycle and are based on reports by manufacturers, providers, consumers and others to the FDA's Adverse Event Reporting System (AERS).... periodic safety information submitted to FDA by manufacturers; information contained in the medical literature; and data from ongoing drug and biologic studies.
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> Included in the summaries may be information on potentially serious, previously unidentified risks, if any are found during the review, as well as known adverse events that occur more often than they did during clinical studies. The summaries will also include a brief discussion of any steps FDA may be taking to address these safety issues.

From a June 15, 2010 *USA Today* article, "New FDA website lets public find drug safety info", by reporter Rita Rubin:

> On the Postmarketing Drug Safety Evaluations site, the FDA plans to share what it has learned about the safety of a new drug or biologic, such as a vaccine, 18 months after approval or after 10,000 patients have used it, whichever comes later.
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> The agency is making a "broad sweep" of adverse-event reports, medical studies and research, and drug utilization databases to look for safety problems, Robert Boucher, an official in the FDA's Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research, said at a news briefing.

For the initial posting, "Postmarketing Drug Safety Evaluation Summaries -- Postmarketing Drug Safety Evaluations completed through the fourth quarter of 2009", provides postmarket safety evaluations for 26 drugs that were approved by the FDA between September 2007 and January 2008.

We applaud the FDA for launching this new web site insofar that it makes available to the public possible emerging drug-safety issues earlier than the agency had in the past.

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