FDA's Sentinel Initiative Project: An Overview, Progress To Date, And Next Steps

Presentation Made At September 17, 2009 FDA Drug Safety Oversight Board Meeting

(Posted by Tom Lamb at www.DrugInjuryWatch.com on October 15, 2009; see http://bit.ly/2quVOs)

At the September 17, 2009 meeting of the FDA Drug Safety Oversight Board (DSB), members heard presentations and discussed four topics:

- An update on the Sentinel Initiative;
- The DSB path forward in 2009 and beyond;
- The CDER Center Director's conversation with the DSB; and,
- A one-year follow-up on issues presented to the DSB.

We were most interested in the update on the FDA's Sentinel Initiative project for monitoring medical product safety, which we last reported on in March 2009.

From the Public Summary for the September 17, 2009 DSB meeting we get the following information about the Sentinel Initiative update:

> The Scientific Lead on FDA's Sentinel Initiative presented an overview, progress to date, and next steps in FDA's Sentinel Initiative. The goal of the Sentinel Initiative is to develop an active electronic safety monitoring system to strengthen FDA's ability to monitor the postmarket performance of medical products. The Sentinel Initiative's intent is to augment, not replace, existing safety monitoring systems, and to enable FDA to access existing automated healthcare data by partnering with healthcare insurance providers, academic institutions, federal and state government agencies, healthcare providers, and other owners of various electronic health records.
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> The Board discussed the following advantages of the Sentinel Initiative:
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> 1. Identifying and evaluating safety issues in near real time
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> 2. Expanding FDA's capacity for evaluating safety issues
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> 3. Improving access to information on subgroups and special patient populations
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> 4. Improving precision of risk estimates because of expanded numbers of patient available for study
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> 5. Actively surveying and identifying an increased risk of common medical product-related adverse events that health care providers may not suspect are related to medical products

As for the make up of the Drug Safety Oversight Board, at the present time it consists of representative from three FDA Centers (Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health) and six Federal Partners (the Agency for Health Care Research and Quality, Centers for Disease Control and Prevention, Department of Defense, Indian Health Service, National Institutes of Health, and Department of Veterans Affairs).

We will continue to monitor developments related this FDA Sentinel Initiative project.

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