How Electronic Medical Records Review Might Help FDA Identify Unsafe Drugs Sooner

Study Says Using Such Data Would Have Resulted In Faster Safety Signal Detection For Increased Risk Of Heart Attacks With Avandia Use

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 15, 2010; see http://bit.ly/9zbG9w)

A recent medical journal article suggests that a systematic review of electronic medical records may have allowed the FDA and others to identify the increased risk for heart attack, or myocardial infarction (MI), with Avandia use as early as 18 months after Avandia came on the market in the U.S.

The December 15, 2009 edition of *Diabetes Care* included the article "Rapid identification of myocardial infarction risk associated with diabetic medications using electronic medical records". From the Abstract for that article:

> Objective: To assess the ability to identify potential association(s) of diabetic medications with myocardial infarction (MI) using usual care clinical data obtained from the electronic medical record.
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> Results: ... After adjustment for potential MI risk factors, relative risk for MI with rosiglitazone was 1.3 (95% CI, 1.1-1.6) compared to sulfonylurea, 2.2 (95% CI, 1.6-3.1) compared to metformin, and 2.2 (95% CI 1.5-3.4) compared to pioglitazone. Prospective surveillance using these data would have identified increased risk for MI with rosiglitazone compared to metformin within 18 months of its introduction with a risk ratio of 2.1 (95% CI 1.2-3.8).
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> Conclusions: ... Our use of usual care electronic data sources from a large hospital network represents an innovative approach to rapid safety signal detection that may enable more effective post-marketing drug surveillance.

We have reported over time about the FDA's Sentinel Initiative project for monitoring medical product safety, the goal of which is to develop an active electronic safety monitoring system to strengthen FDA's ability to track the postmarket performance of medical products.

This recent study about identifying the heart attack risk associated with Avandia by use of electronic medical records seemingly indicates that the Sentinel Initiative will be a good means by which to augment existing drug safety monitoring systems.

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.
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