



November 24, 2009 - Topic: Patient Safety

Researchers Urge FDA To Create Database To Monitor Rx Drug Safety

Federal regulators should create a public database to improve the system for monitoring prescription drug safety, according to an *Archives of Internal Medicine* study published Monday, the *New York Times* reports.

The researchers write that the database could continuously pool and aggregate information from clinical trials to create a real-time picture of a drug's benefits and risks. They said officials should strive to make the database publicly available for consumers, physicians and researchers.

To develop their recommendations, the study authors examined information on Merck's arthritis pain medication Vioxx. The company pulled Vioxx from the market in 2004 after studies showed that the drug increased the risk of heart attack or stroke.

According to the researchers, continuous real-time drug monitoring would have alerted Merck to Vioxx's risk years before the company withdrew the medication.

The researchers said their public database proposal could serve as a safety monitoring model for all new prescription drugs.

Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, said new legislation would be necessary to establish such a drug monitoring database (Singer, *New York Times*, 11/24).

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