FDA And Novartis Announce A Label Change For Iron Chelating Drug Exjade In Mid-February 2010

Includes A New "Black Box" Warning About Renal Impairment, Liver Failure, And Gastrointestinal Hemorrhage

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 16, 2010; see http://bit.ly/cI2Ady)

In mid-February 2010 the FDA and Novartis announced a change to the Prescribing Information (PI) -- also referred to as the package insert or label -- for Exjade (deferasirox), a drug indicated for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older.

From this MedWatch 2010 Safety summary, "Exjade (deferasirox): Boxed Warning", in relevant part:

> New language was added to the Contraindications, Warnings and Precautions, and Drug Interactions sections of the PI, including a Boxed Warning, that the product may cause:
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> - renal impairment, including failure
> - hepatic impairment, including failure
> - gastrointestinal hemorrhage
>
> In some reported cases, these reactions were fatal. These reactions were more frequently observed in patients with advanced age, high risk myelodysplastic syndromes, underlying renal or hepatic impairment or low platelet counts. Exjade therapy requires close patient monitoring, including measurement of serum creatinine and/or creatinine clearance as specified in the PI and serum transaminases and bilirubin as specified in the PI.

For additional information, this February 2010 FDA MedWatch document referred us to the so-called "Dear Doctor" letter dated February 17 from Novartis and the revised Exjade Prescribing Information (January 2010 version).

As some of you will know, Exjade has been under scrutiny by the FDA and Health Canada over safety concerns for some time, now. Here is a timeline showing some of this regulatory "attention":

September 2007: The FDA states in an FDA Drug Safety Newsletter that the agency had received 115 reports of suspected adverse drug reactions (ADR) in association with Exjade use, including 17 deaths in adults.

September 2009: The FDA issues its "Early Communication about an Ongoing Safety Review of Deferasirox (marketed as Exjade)", which includes this information:

> FDA is reviewing adverse event information for Exjade from a database that tracks all patients who are prescribed Exjade and a company-sponsored global safety database. This information suggests there may be a greater risk for adverse events such as kidney failure, gastrointestinal hemorrhage (potentially fatal bleeding) and deaths in patients with myelodysplastic syndrome (MDS) compared to patients without these conditions.

November 2009: Novartis sends out a "Dear Doctor" letter in Canada about Exjade with this Suject line: "Use of EXJADE (deferasirox) in Patients Diagnosed with Myelodysplastic Syndrome (MDS) and in Elderly Patients regarding Renal Events and Gastrointestinal Hemorrhage (Fatal in Rare Cases)")".

We will continue to monitor and report about the safety profile of Exjade going forward.

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