Drug Injury Watch: Xarelto - Liver Side Effects: Will New Warning Be Added To Drug Label?

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 8, 2015)

This is not the first time we have written about Xarelto side effects involving liver failure.

Back in November 2014 we posted this article, "Xarelto: Drug-Induced Liver Injury Warning Should Be Added To Drug Label Prescribing Information For Xarelto Say Medical Researchers", which reported on a medical journal article about two patients who experienced severe liver damage while using Xarelto.

More recently, in the August 2015 edition of the *Health Product InfoWatch* publication from Health Canada. there appeared this article, "Xarelto (Rivaroxaban) and liver injury" from which we get the following information:

> • As of Sept. 30, 2014, Health Canada received 61 reports of liver-related adverse reactions (ARs) involving [Xarelto (rivaroxaban)]. However, the majority of reports lacked important information such as dosing information, duration of exposure, liver biochemistries, comorbidities and concomitant medications.... Consequently, a causal relationship between [Xarelto (rivaroxaban)] and liver injury could not be established in most Canadian cases.
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> • Health Canada's review of [Xarelto (rivaroxaban)] and liver injury identified 16 published cases of liver injury suspected of being associated with [Xarelto (rivaroxaban)] use. Patients were 41 to 91 years of age and received daily doses of rivaroxaban between 10 to 20 mg. Most patients were being treated for knee or leg surgery. Latency time from exposure to the first signs or symptoms of liver injury ranged from 3 days to 2 months. In addition, varying degrees of transaminase elevations suggest the occurrence of cholestatic, hepatocellular and mixed patterns of liver injury. Given the varied dose, latency period and pattern of liver injury, these cases may be idiosyncratic. All but one patient recovered. [footnotes omitted]

Given these numerous case reports made to Health Canada and documented in medical articles, one wonders whether the responsible drug company, Janssen Pharmaceuticals, Inc., should increase the drug label warnings about hepatic / liver side effects such as acute liver failure, which can be fatal in some instances.

[Read this article in full at original source]

Earlier articles by attorney Tom Lamb on the Side Effects Blog:

- Xarelto: Drug-Induced Liver Injury Warning Should Be Added To Drug Label Prescribing Information For Xarelto Say Medical Researchers
- Eliquis And Xarelto, Like Pradaxa, Linked To Serious Bleeding Events Due To Fact No Antidote Available
- Drug Safety Significance Of Adverse Reactions Reports For Xarelto Blood Thinner Pill Is Uncertain, At Best

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