Drug Injury Watch: Hep C Drugs Viekira Pak And Technivie: FDA Warnings About Liver Injury

(Posted by Tom Lamb at <u>www.DrugInjuryWatch.com</u> on November 26, 2015)

On October 22, 2015 the FDA issued this announcement, "Hepatitis C Treatments Viekira Pak and Technivie: Drug Safety Communication - Risk of Serious Liver Injury", from which we get this warning information summary:

Since the approvals of Viekira Pak in December 2014 and Technivie in July 2015, at least 26 worldwide cases submitted to FAERS were considered to be possibly or probably related to Viekira Pak or Technivie. In most of the cases, liver injury occurred within 1 to 4 weeks of starting treatment. Some of the cases occurred in patients for whom these medicines were contraindicated or not recommended (see the Drug Safety Communication Data Summary section). FAERS includes only reports submitted to FDA, so there are likely additional cases about which FDA is unaware.

We get an immediate reaction from AbbVie, the drug responsible for these new hepatitis C drugs, from this October 22, 2015 article by Peter Loftus published by *The Wall Street Journal*, "Shares fall on warning Viekira Pak and Technivie could cause injury in patients with underlying liver disease":

The FDA said it suspects the drugs may have caused the liver injuries because of a "temporal association" after patients started using the drugs, and some patients who stopped using them saw symptoms go away.

AbbVie said a causal relationship between the treatments and the adverse events hasn't been established, but the drugs couldn't be ruled out as a cause. The North Chicago, Ill., company is updating the prescribing labels for the drugs to warn against their use in a subset of hepatitis C patients with more advanced cirrhosis, and to advise doctors to assess whether patients have liver dysfunction before starting treatment.

For more details about this new drug-induced liver injury development, we refer you to the "FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie" document.

For more information, you can read the Prescribing Information documents, or drug labels, for Viekira Pak and Technivie, which were revised in October 2015.

We will continue to follow this developing drug injury issue concerning the relatively new hepatitis C drugs Viekira Pak and Technivie.

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Attorney <u>Tom Lamb</u> 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. <u>http://www.DrugInjuryWatch.com</u>