

## Drug Injury Watch: Sovaldi / Harvoni: "Black-Box" Warning About Hepatitis B Reactivation

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on February 17, 2017)

In February 2017 a so-called "black-box" warning was added to the drug labels for Harvoni, Sovaldi, Technivie, Viekira Pak, and other direct-acting antivirals, warning doctors and patients that cases of hepatitis B virus (HBV) reactivation have been reported. Further, it states that some of those cases resulted in fulminant hepatitis, hepatic failure, and death.

For more details, we get the following from the Warnings and Precautions part of the February 2017 revised Sovaldi drug label:

### 5.1 Risk of Hepatitis B Virus Reactivation in Patients Coinfected with HCV and HBV

Hepatitis B virus (HBV) reactivation has been reported in HCV/HBV coinfecting patients who were undergoing or had completed treatment with HCV direct acting antivirals, and who were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death....

HBV reactivation is characterized as an abrupt increase in HBV replication manifesting as a rapid increase in serum HBV DNA level. In patients with resolved HBV infection, reappearance of HBsAg can occur. Reactivation of HBV replication may be accompanied by hepatitis, i.e., increases in aminotransferase levels and, in severe cases, increases in bilirubin levels, liver failure, and death can occur.

Back in December 2016 Health Canada issued this document, "Summary Safety Review -- Direct-acting antivirals -- Assessing the Potential Risk of Hepatitis B Virus Reactivation", from which we get the following key points:

- Health Canada carried out a review of the potential risk of hepatitis B virus (HBV) reactivation with the use of DAAs. The review was triggered by reports that patients infected with both HBV and HCV may experience a reactivation of their HBV infection if DAAs are used to treat their HCV infection. These reports were identified by the European Medicines Agency (EMA).
- Health Canada's review concluded that there is a potential risk of HBV reactivation in patients coinfecting with both HBV and HCV, and the use of DAAs. Health Canada has recommended that the safety information for all DAAs be updated to inform about this potential risk.

We will continue to monitor this aspect of the safety profile of Harvoni, Sovaldi, Technivie, Viekira Pak, and other direct-acting antivirals (DAAs) used increasingly in the US and elsewhere to treat the hepatitis C virus (HCV).

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***Earlier Harvoni / Sovaldi / Viekira Pak / Technivie articles by attorney Tom Lamb on the [Side Effects Blog](#):***

- [Newer Hepatitis C Drugs Harvoni And Sovaldi Could Cause Liver Failure](#)
- [Is The Risk Of Liver Cancer Increased From Use Of Harvoni Or Sovaldi?](#)

- [Black-Box Warning For Harvoni, Sovaldi, Viekira Pak: Hepatitis B Risk](#)
- [Harvoni / Sovaldi Risks: Liver Cancer Return, Hepatitis B Reactivation](#)

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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>