

# FDA warns of deadly liver damage with AbbVie hepatitis drugs

October 22 2015, byMatthew Perrone

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Federal health officials are warning doctors and patients that two hepatitis C drugs from AbbVie can cause life-threatening liver injury in patients with advanced forms of the disease.

The Food and Drug Administration said Thursday it will require AbbVie to add new warnings to Viekira Pak and Technivie after reported deaths and liver transplants in patients who already had liver damage caused by hepatitis C.

The warning could reshape the growing field of high-priced drugs to treat the virus, which also includes Gilead Sciences' blockbuster medications Sovaldi and Harvoni.

Jefferies analyst Brian Abrahams wrote in an investment note that the warning is a "moderate positive" for Gilead Sciences. But he added that AbbVie's Viekira Pak was already expected to be "displaced" by a similar drug from Merck & Co. Inc. next year.

Shares of North Chicago, Illinois-based AbbVie Inc. plummeted \$5.56, or 10 percent, to close at \$48.27 in trading Thursday.

Nearly 3 million Americans have the virus, which develops slowly over decades and, if left untreated, can cause liver failure and liver cancer, requiring transplant.

The FDA said in an online posting that AbbVie's drugs have been linked

to multiple cases of severe liver damage—some of them fatal—in patients who already had liver cirrhosis, irreversible scarring of the organ. The agency determined 26 such events were likely related to the drugs, with the liver damage usually occurring within four weeks of starting treatment.

AbbVie said in a statement it is adding a warning to the drugs that they must not be used in patients with moderate to severe liver impairment.

"Patient safety is of the utmost concern to AbbVie," the company said in an emailed statement.

AbbVie's drugs are part of a new wave of pill-only combinations that cure more patients and cause fewer side effects than older hepatitis C treatments, which required injections and caused flu-like side effects.

Viekira Pak treats the most common form of hepatitis C, known as genotype 1, which accounts for about 75 percent of all U.S. cases. Technivie, approved in July, treats one of the least common forms of hepatitis C.

Gilead Sciences initially dominated the space, raking in over \$9.4 billion in sales for Sovaldi in its first full-year on the market. The company followed that approval with the launch of a combination pill, Harvoni, to treat a much broader group of hepatitis C patients.

While doctors and patients have embraced the new drugs, insurers have pushed back over their sky-high prices—generally \$83,000 or more for one course of treatment.

The launch of AbbVie's pill, Viekira Pak, was welcomed as a much-needed competitor in the field. Since then, providers have been forcing Gilead and AbbVie to compete on price to get preferred standing in their

formularies of approved drugs, and have been winning substantial discounts.

Express Scripts, the nation's largest provider of pharmacy benefits, has thrown its weight behind AbbVie's drugs, refusing to cover competing products from Gilead and Johnson & Johnson.

Shares of Foster City, California-based Gilead Sciences Inc. rose \$5.87, or 5.8 percent, to close at \$107.60.

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