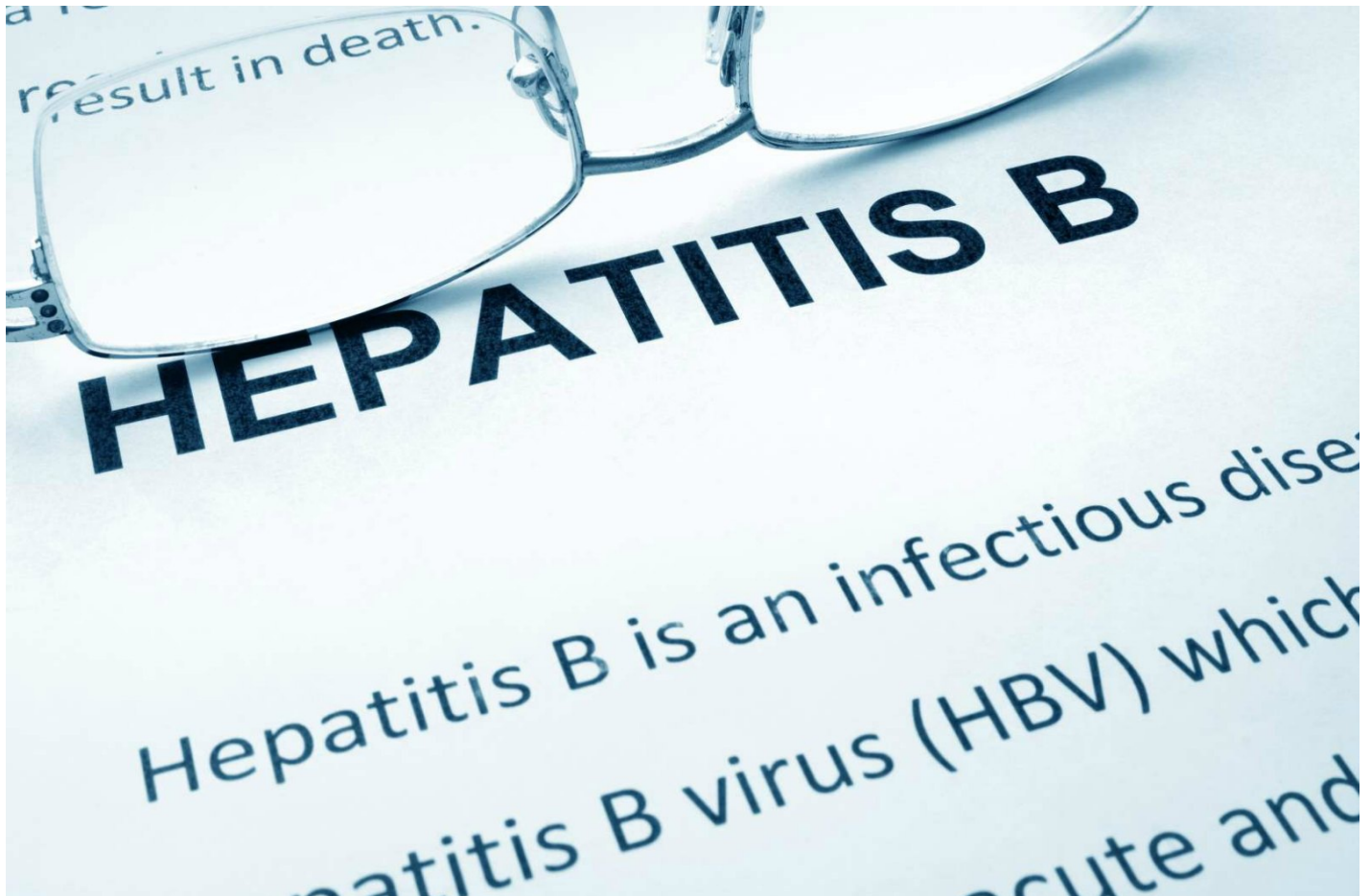


Chronic Hepatitis B: Battling A Global Killer With A New Drug

Emory University



Hepatitis B, a virus that inflames the liver, is one of the top ten killers worldwide. Globally, about 350 million people, about 5 percent of the world's population, are chronic carriers, and thousands die each year from complications of chronic hepatitis B virus (HBV) infections. Due to a successful vaccine and better treatment options these rates are declining. But for HBV patients who show signs of liver damage, are pregnant, or who have HIV as well, the medications normally used to treat HBV might be harmful.

The drug telbivudine (marketed under the tradename Tyzeka®) is now available to help this group. Invented by Raymond Schinazi, PhD, Director of the Laboratory of Biochemical Pharmacology at Emory, Tyzeka® is the only FDA-approved hepatitis B drug that is selectively active against HBV. Telbivudine, which was approved by the FDA in 2006, works by decreasing the amount of HBV in the body. It does not cure HBV but may prevent complications. Tyzeka® (marketed as Sebivo® in Europe) is a synthetic nucleoside analogue that was codeveloped by Idenix Pharmaceuticals, Inc. and Novartis Pharma AG, which has exclusive worldwide commercialization rights to the drug.

"If you have someone who is co-infected with HIV and you treat them with a different Hep B drug, you can get an emergence of resistant HIV. With this drug, you don't have to worry about that. It's inactive against HIV in vitro and in humans," Schinazi says. "It is also one of the few drugs that can be used to treat pregnant HBV infected women."

“ *HBV can be passed from person to person through contact with blood or bodily fluids, from mothers to their infants, or by sharing infected needles, similar to HIV. In the US, HBV is largely a disease of young men aged 25 to 44, a population also at risk for HIV.*

While about 1.25 million Americans are HBV carriers, only a fraction of them are receiving oral HBV medications.

Tyzeka® is bringing hope to people living with chronic hepatitis B, which can progress to fatal cirrhosis and/or liver cancer, said Timothy Block, PhD, president of the Hepatitis B Foundation.

Through a settlement agreement with Idenix Pharmaceuticals (IDIX), a company co-founded by Schinazi in 1998, Emory is receiving payments for telbivudine-containing products that are expected to total at least \$6 million by 2018. Idenix settled a long-standing dispute with Emory and the University of Alabama at Birmingham related to telbivudine in 2008. The company made a one-time payment to Emory of \$1.6 million and agreed to additional ongoing royalty and minimum payment obligations.

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