Rare Heart Risk From Sovaldi and Harvoni

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Hepatitis C virus (HCV) regimens containing Gilead Sciences' Sovaldi (sofosbuvir)—including Harvoni (ledipasvir/sofosbuvir)—may in rare cases cause a severe slowing of the heart. The U.S. Food and Drug Administration (FDA) has found that those who are also taking the heart medication Cordarone (amiodarone) are at risk; in 2015, Gilead updated its label of the two hep C treatments to caution about the danger of combining Sovaldi with the heart drug.

Andrew J. Muir, MD, chief of the division of gastroenterology at Duke University School of Medicine, stresses that the incidents of slow heart rate among people taking Sovaldi–containing regimens come only from case reports. "I am encouraged that sofosbuvir has been extensively studied in industry trials and real-world registries and has been very well-tolerated," he says. "But studies cannot predict the experience of every patient, and for me these case reports highlight the need to be vigilant in patients with serious medical problems and monitor them closely on treatment."

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