Hep C, HIV Drug-Drug Interaction Studies Must Be a Priority, Activists Say

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The Hepatitis C Community Advisory Board (HCAB), in a statement released Thursday, February 16, stressed their belief that it is possible to conduct such drug-drug interaction studies prior to U.S. Food and Drug Administration (FDA) approval without delaying development of novel therapies for HCV.

Because many emerging HCV drugs, frequently referred to as direct-acting antivirals (DAAs), are broken down (metabolized) by the same enzyme pathways responsible for processing many other medications used by people living with hepatitis C, including those who are also HIV positive, thoroughly exploring potential drug-drug interactions and ways to circumvent problems is important. Left unchecked, interactions can significantly decrease the effectiveness of some drugs while potentially increasing the risk of serious side effects from other drugs.

Early knowledge of interactions between DAAs and HIV-treating antiretrovirals is particularly crucial, given that roughly one third of people living with HIV are coinfected with HCV and are becoming increasingly dependent on the rapid availability of new DAAs.

“In recognition of the suboptimal efficacy and tolerability of peginterferon and ribavirin, rapid trajectory of liver disease progression and increasing mortality from HCV-related complications among HIV/HCV coinfected patients,” the HCAB statement reads, “regulators in the [United States] and the [European Union should] encourage sponsors to conduct trials in HIV/HCV coinfected patients prior to approval for [people living with HCV but not HIV].”

The HCAB statement stems from concerns related to the recent discovery of drug-drug interactions between Merck’s Victrelis (boceprevir) and Norvir (ritonavir)-boosted protease inhibitors used to treat HIV infection. “Although we commend [Merck] for opening one of the first coinfection trials with a DAA, we were outraged that Merck chose not to conduct [drug-drug interaction studies] with commonly used antiretroviral agents prior to launching the trial, and prior to gaining approval for boceprevir.”

“Vertex and Tibotec,” the statement authors add, “were able to bring [Incivek] telaprevir to market with a much fuller portfolio of [drug-drug interaction] data, although both drugs were developed within the same timeframe.”

HCAB is asking FDA, the European Medicines Agency (EMA) and pharmaceutical companies to work together to minimize potential harm to people living with HCV, including people coinfected with HIV and HCV, from uncharacterized drug-drug interactions.

“Furthermore,” the statement concludes, “we call upon sponsors to perform [drug-drug interaction] studies (as indicated by metabolic profile of their drug or drugs) with [Department of Health and Human Services, European AIDS Clinical Society and World Health Organization]-recommended antiretroviral agents for first-line, and treatment-experienced HIV/HCV coinfected people prior to approval, and strongly encourage studies of hormonal contraceptives, methadone, buprenorphine, lipid lowering agents, immunosuppressive drugs, herbal remedies, and commonly prescribed psychiatric medications.”

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