



Infectious Diseases Society of America



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Division of Dockets Management (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

## **RE: Docket No. FDA-2013-D-1170, "Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; Draft Guidance for Industry; Availability"**

The Infectious Diseases Society of America (IDSAs) and the HIV Medicine Association (HIVMA) appreciate the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance on "Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment." IDSAs and HIVMA members care for and manage patients with and at risk for infectious diseases, including hepatitis C virus (HCV), HIV infection and patients who are co-infected with HIV and HCV. IDSAs collaborated with the American Association for the Study of Liver Diseases (AASLD) to develop guidance for the treatment of HCV ([www.HCVguidelines.org](http://www.HCVguidelines.org)), which we continue to update as new therapies and evidence on existing therapies become available.

IDSAs and HIVMA have been extremely encouraged by the development of new therapies that can cure HCV infection in the vast majority of patients — a significant clinical advancement over prior HCV therapies. In the U.S., nearly 4 million persons are estimated to be infected with HCV and approximately 50 to 75 percent are unaware of their status. Approximately 20,000 individuals are newly infected each year. New cures for this virus, which if not treated can lead to debilitating and costly conditions including cirrhosis, liver cancer, and liver transplants, represent a tremendous new scientific advancement with the potential to improve and save the lives of millions of patients. IDSAs supports federal policies to continue to improve and better understand treatment options for persons infected with HCV and to facilitate development of new treatment options to lower drug costs. We are pleased to offer specific comments regarding standardized reporting of resistance analyses and the enrollment of HIV-infected patients in HCV studies. In addition, we would like to emphasize the importance of additional treatment options for the purpose of improving access to treatment.

### Standardized reporting of resistance analyses

We encourage the FDA to address the current differences in reporting resistance analyses. There is significant variation in reporting and thus in the analyses that are ultimately reported to FDA and in package inserts. A more standardized approach in which all clinical outcomes are reported based upon

population-level sequencing would provide far more useful data for FDA, HCV researchers, and clinicians treating HCV infected patients. Standardized, clearly articulated methodologies for resistance associated variance (RAV) testing, and when possible the clinical significance, should be a component of this effort. We encourage FDA to use the precedence for such an approach found in current HIV resistance reporting policy as a model for addressing this issue with HCV.

#### Enrollment of HIV-infected patients in HCV studies

We are pleased that HIV-infected patients are now being enrolled in HCV studies rather than being excluded. About 30% of individuals living with HIV are co-infected with HCV and it is important to understand the safety and efficacy of new HCV treatments for these patients, and in particular, their potential interactions with HIV medications. As progress on this front continues, it is important that a sufficient number of HIV-infected patients be included to address the drug interaction issues and other issues that remain unique to co-infected patients. While we appreciate that the draft guidance allows for the number of patients to vary depending on drug interactions, we encourage the FDA to consider requiring a specific minimum number of HIV-infected patients enrolled to ensure safety with confidence.

#### Access to new HCV treatments

IDSA and HIVMA believe it is critical that patients be able to access new HCV therapies so that as many as possible can benefit. In October 2015, IDSA and AASLD strengthened the HCV treatment guidance to recommend initiating treatment in nearly all patients with hepatitis C.<sup>1</sup> Unfortunately, due to severe access restrictions in part driven by cost, too few patients have been able to benefit from the new HCV therapies. Increasing the number of HCV treatment options available on the market will improve treatment uptake by lowering costs and providing additional options for those with pharmacological obstacles with existing regimens. IDSA and HIVMA encourage FDA to continue to promote the research and development of new HCV medications.

Once again, IDSA and HIVMA greatly appreciate the FDA's attention to these important issues and the opportunity to provide comments. Should you have any questions, please feel free to contact IDSA's Vice President for Public Policy and Government Relations, Amanda Jezek at [ajezek@idsociety.org](mailto:ajezek@idsociety.org) or HIVMA's Executive Director, Andrea Weddle at [aweddle@hivma.org](mailto:aweddle@hivma.org).

Sincerely



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IDSA President



Carlos del Rio, MD, FIDSA  
Chair, HIVMA Board of Directors

**About IDSA**

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA) vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, and, finally, emerging infectious syndromes such as Ebola virus fever, enterovirus D68 infection, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Zika virus disease, and infections caused by bacteria containing the New Delhi metallo-beta-lactamase (NDM) enzyme that makes them resistant to a broad range of antibacterial drugs.

**About HIVMA**

HIVMA is housed within IDSA and represents more than 5,000 physicians, scientists and other health care professionals working on the frontlines of the HIV epidemic across the U.S. and in countries around the globe.