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December 19, 2012

Dr. Robert Cosby c/o United States Preventive Services Task Force (USPSTF) Agency for Healthcare Research and Quality (AHRQ) 540 Gaither Road Rockville, MD 20850

RE: USPSTF Draft Recommendation Statement – Screening for Hepatitis C Virus (HCV) Infection in Adults

Dear Dr. Cosby:

The HIV Medicine Association (HIVMA) appreciates the opportunity to provide comments on the USPSTF's draft updated recommendation statement on screening for hepatitis C virus (HCV) infection in adults. HIVMA represents nearly 5,000 clinicians and researchers on the front lines of the HIV/AIDS epidemic in the U.S. and abroad whose clinical management and research on common comorbidities of HIV disease includes HCV infection.

We applaud and agree with your upgrading of the recommendation for HCV screening of persons with risk factors from a grade "I" to a grade "B." However, for the birth cohort HCV screening recommendation, we strongly urge the Task Force to reconsider the "C" grade level and revisit the considerable evidence to support strengthening the recommendation.

In addition, we are concerned that the draft HCV screening recommendation neglects to include patients with an HIV diagnosis among the high risk population that should be screened for HCV infection.¹ It is estimated that 30-40% of the HIV-infected population in the United States is co-infected with HCV, although the prevalence varies with risk factor for transmission. Among HIV-infected injection drug users and hemophiliacs, 70-95% may be co-infected with HCV.² We urge the Task Force to include individuals with a diagnosis of HIV infection among the groups considered to be at risk of HCV infection and recommended for screening.

As the Task Force recognizes in the evidence review, there is an accurate diagnostic test for HCV and there is considerable morbidity and mortality benefit

from successful treatment.³ In addition, in finalizing its recommendation, we ask the task Force to consider that:

- Antibody screening test results can be confirmed without measurable risk. The concern that
 a positive screening test might result in frequent unnecessary and harmful procedures is
 mitigated by this;
- As is now abundantly clear with regard to HIV screening, there is compelling evidence that HCV screening based on risk factors has been inadequate, considering that three out of four HCV infected persons are unaware of their status;⁴
- The Centers for Disease Control and Prevention (CDC) analysis projects birth cohort testing would identify approximately 800,000 new infections and save 121,000 lives. ⁵ Testing more people to find those 800,000 does not diminish the benefits and the additional cost has already been found to be easily justified. ⁶
- The prevalence of HCV infection in the 1945 to 1965 birth cohort (4%) is similar to the prevalence among persons with a transfusion before 1992 (6%), ⁷ and the latter is one of the groups for whom the Task Force recommends a "B" grade for screening. Therefore, the magnitude of the overall health benefit is comparable for both populations.

Also, the benefits of successful HCV treatment are likely to soon increase as clinical outcomes are expected to dramatically improve with the availability of new and improved therapeutics that have higher success rates, and are more tolerable due to shorter treatment regimens and fewer side effects. Conversely, the "C" grade can cause harm to individuals by perpetuating late diagnosis and disease progression in the United States.

We appreciate the opportunity to provide comments on the draft recommendation statement. Please feel free to contact HIVMA Policy Officer, Kim Miller, at (703) 740-4957 or kmiller@hivma.org if we can provide further information.

Sincerely,

Michael Horberg, MD, MAS, FACP, FIDSA

Chair, HIVMA Board of Directors

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¹ Aberg et al, "Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus: 2009 Update by the HIV Medicine Association of the Infectious Diseases Society of America,"CID 2009:49 (1 September) p. 665.

² Fox, Rena, MD, "Hepatitis C Infection: Guide for HIV/AIDS Clinical Care, HRSA HIV/AIDS Bureau June 2012, accessed online 12/7/2012 at (http://www.aidsetc.org/aidsetc?page=cg-616 hepatitis c&).

³ Chou, R. et al. Comparative Effectiveness of Antiviral Treatment for Hepatitis C Virus Infection in Adults: A Systematic Review. First published in Annals of Internal Medicine on November 27, 2012 (Ann Intern Med 2012; http://www.annals.org).

⁴ Institute of Medicine of the National Academies. Hepatitis and liver cancer: a national strategy for prevention and control of hepatitis B and C. Colvin HM and Mitchell AE, ed. Updated January 11, 2010. Available at: http://www.iom.edu/Reports/2010/Hepatitis-and-Liver-Cancer-A-National-Strategy-for-Prevention-and-Control-of-Hepatitis-B-and-C.aspx (accessed 12/13/2012).

⁵ Smith BD, Morgan RL, Beckett GA, Falck-Ytter Y, Holtzman D, Ward JW. Hepatitis C Virus Testing of Persons Born During 1945 to 1965: Recommendations From the Centers for Disease Control and Prevention. Ann Intern Med. 2012; 157.

⁶ Rein DB, Smith BD, Wittenborn JS, Lesesne SB, Wagner LD, Roblin DW et al. The cost-effectiveness of birth-cohort screening for hepatitis C antibody in U.S. primary care settings. Ann Intern Med. 2012;156:263-70.

⁷ Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. Ann Intern Med. 2006;144:705-14.

⁸ Jesudian et al, "Advances in the Treatment of Hepatitis C Virus Infection," Gastroenterol Hepatol (N Y) 2012 February; 8(2): 91–101.

⁹ Chak, E, et. al. Hepatitis C Virus Infection In USA: An Estimate of True Prevalence. Liver Intl. 2011;1096 -1098.