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November 10, 2014

Mr. James J. Berger

Senior Advisor for Blood and Tissue Safety Policy Office of HIV/AIDS & Infectious Disease Policy Office of the Assistant Secretary for Health U.S. Department of Health & Human Services

1101 Wootton Pkwy, Suite 250  
Rockville, MD 20852

Subject: HIVMA Public Comments to the November 13-14 Meeting of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)

Dear Mr. Berger and Advisory Committee Members:

The HIV Medicine Association (HIVMA) appreciates the opportunity to provide public comments to the Committee, in support of your work to advance evidence-based blood donation policy. HIVMA represents more than 5,000 medical providers and researchers working on the frontlines of the HIV epidemic across the United States. The Association's mission is to promote access to quality HIV care and to advocate policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice.

In April, 2012 and again at a December, 2013 meeting of the ACBTSA, we expressed our strong support for the National Institutes of Health's (NIH's) planned collection and analysis of evidence, opinions and perspectives regarding the current blood donation policy for men who have sex with men (MSM). More than ample time has passed for open and transparent evidence reviews and findings to inform science-based Committee recommendations for reforming the FDA's current blood donor deferral criteria. Specifically – recommendations for shifting the focus to risk behavior-based criteria and maintain the safety of the blood supply without excluding low-risk MSM from donating blood.

HIVMA began calling for changes to the FDA blood donor deferral criteria in 2004 to reflect advances in blood testing technology and scientific knowledge regarding transmission of HIV disease. Changes to the deferral criteria are warranted and overdue given that HIV infection is transmitted through unprotected sexual contact regardless of sexual orientation. There is no rational or scientific justification for maintaining a lifetime ban on blood donation for gay men, particularly given the guidance's 12-month exclusion for individuals who acknowledge having had sexual contact with an individual with HIV infection.

The current lifetime deferral of all gay men encourages the homophobia and discrimination that contributed to a slow and woefully inadequate early response to HIV infection in the 1980's and continues to plague the implementation of HIV prevention, screening and care programs today. HIVMA recommends that the blood donor screening procedures be revised to ask all potential donors to exclude themselves if they have tested positive for HIV, engaged in unprotected sex with a partner of unknown HIV status or if they have recently used a syringe not prescribed by a physician to take drugs or steroids.

We urge the Committee not to further delay issuance of science-based recommendations for updating the blood donor deferral criteria to screen based on risk behavior rather than sexual orientation. Public policy across federal agencies must be grounded in science and informed by what we have learned regarding HIV transmission over the past 30 years. Sound public policy is critical to mounting our most effective response to the HIV/AIDS epidemic, including reform of outdated stigmatizing and discriminatory policies.

We would be pleased to serve as a resource to the Committee as you move forward with your important work. If you have any further questions, please feel free to contact Ms. Kimberly Miller, Policy Officer at the HIVMA at [kmiller@hivma.org](mailto:kmiller@hivma.org) or (703) 740-4957.

Sincerely,



Adaora Adimora, MD, MPH, FIDSA  
Chair, HIVMA Board of Directors

cc: Ronald O. Valdiserri, MD, MPH, Deputy Assistant Secretary for Health, Infectious Diseases

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<sup>1</sup>“National Institutes of Health Comment Request on Proposed Study of the Current Blood Donation Policy for Men Who Have Sex with Men” (Federal Register Notice: Vol. 77, No. 36, accessed online 11/5/2013 at <http://www.gpo.gov/fdsys/pkg/FR-2012-02-23/html/2012-4211.htm>)

<sup>2</sup>HIVMA Policy Statement on Donor Screening Guidelines for Blood Donation, September, 2004 (accessed online 11/5/2014 at: [http://www.hivma.org/Donor\\_Screening\\_Guidelines\\_for\\_Blood\\_Donation.aspx](http://www.hivma.org/Donor_Screening_Guidelines_for_Blood_Donation.aspx))