

HIVMA

hiv medicine association

66 canal center plaza suite 600 /alexandria, va 22314  
703-299-1215 /1703-299-0473 /hivma@society.org /www.hivma.org

November 8, 2004

## board of directors

## chair

Paul Volberding, MD  
University of CA, San Francisco  
San Francisco VA Medical Center  
Oncology

## vice chair

Daniel R. Kuritzkes, MD  
Brigham and Women's Hospital  
Infectious Diseases

## IDSA board representative

Michael S. Saag, MD  
Univ. of Alabama at Birmingham  
Infectious DiseasesJudith Aberg, MD  
Bellevue Hospital Center  
New York University  
Infectious DiseasesNancy Angoff, MD, MPH  
Yale University School of Medicine  
Yale-New Haven Hospital  
Internal MedicineStephen Becker, MD  
Pacific Horizon Medical Group, Inc.  
University of CA, San Francisco  
Internal MedicineNicholas C. Bellas, MD  
Southwest Infectious Disease  
Associates  
Infectious DiseasesRafael E. Campo, MD  
University of Miami School of  
Medicine  
Infectious DiseasesSusan Cu-Uvin, MD  
Miriam Hospital  
Brown University  
OB/GYNFrederick M. Hecht, MD  
University of CA, San Francisco  
San Francisco General Hospital  
Internal MedicineDeborah Konkle-Parker, FNP, PhD  
University of Mississippi Medical Center  
Nurse PractitionerJeffrey Nadler, MD  
University of South Florida  
Tampa General Hospital  
Infectious DiseasesKimberly Smith, MD, MPH  
Rush University Medical Center  
Infectious DiseasesAnita Vaughn, MD  
Newark Department of Health  
Internal MedicineBruce Williams, MD, MPH  
University of NM School of Medicine  
Family Practice

## pediatric ID society liaison

Mabeen Rathore, MD  
University of FL Health Science  
Center  
Pediatric ID & Immunology

## executive director

Christine Lubinski

Lester M. Crawford, D.V.M., Ph.D.  
Acting Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Crawford:

I am writing on behalf of the HIV Medicine Association (HIVMA) Board of Directors and our more than 2,700 physician, scientist, and other health care professional members who devote their careers to HIV/AIDS. An important component of our mission is to promote public policies informed by science. It is our strong commitment to sound public policies that spurred the development of the enclosed policy statement on donor screening guidelines for blood donation.

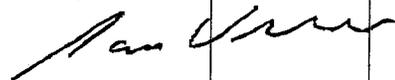
We are writing to request that the Food and Drug Administration (FDA) grant serious consideration to updating its HIV donor screening recommendations as reflected in the HIVMA policy statement. Given the advances in HIV testing capabilities and current knowledge regarding HIV transmission, the lifetime exclusion of certain populations such as men who have sex with men and injection drug users is discriminatory and unnecessary. Furthermore, the current recommendations needlessly limit and strain the donor pool while promulgating the misconception that sexual orientation itself is a primary risk factor for the transmission of a deadly infectious disease.

As you know, the FDA approved the Nucleic Acid Amplification Test (NAT) to screen whole blood donors for HIV infection and hepatitis C virus (HCV) in 2002. The NAT reduced the window period for detecting HIV infection to 12 days, and a recent study confirmed that the NAT has prevented the transmission of HIV-1 through blood donation.<sup>1,2</sup> In October 2004, the FDA released guidelines for industry that recommended widespread adoption of the NAT.<sup>3</sup> Despite these advances, the FDA continues to exclude any man who has had sex with another man since 1977 from donating blood.

We urge the FDA to review all of its screening policies for blood, tissue and organ donation, which contain different and, from our point of view, inappropriate exclusionary criteria for donations from men who have sex with men. We see no scientific justification to recommend different windows of time for donor exclusion, and encourage the FDA to adopt a consistent, science-based approach to donor screening as we propose for blood donation.

Please feel free to contact HIVMA Executive Director Christine Lubinski at 703-299-1215 to discuss this issue further.

Sincerely,



Paul Volberding, MD  
Chairman, HIVMA Board of Directors

cc: HIVMA Board of Directors  
Kenrad E. Nelson, M.D.  
Chairman, FDA Blood Products Advisory Committee  
Linda A. Smallwood, Ph.D.  
Executive Secretary, FDA Blood Products Advisory Committee

<sup>1</sup> FDA Talk Paper: *FDA Approves First Nucleic Acid Test (NAT) System to Screen Whole Blood Donors for Infections with Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)*. February 28, 2002. Available online at: <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01140.html>.

<sup>2</sup> Stramer SL, Glynn SA, Kleinman SH, et al. Detection of HIV-1 and HCV infections among antibody-negative blood donors by nucleic acid-amplification testing. *N Engl J Med* 2004;351:760-8.

<sup>3</sup> FDA. *Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV*. October 2004. Available online at....



hiv medicine association

## Policy Statement on Donor Screening Guidelines for Blood Donation

Approved September 30, 2004

The HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America represents more than 2,600 physicians, scientists and other health care professionals who practice on the frontline of the HIV/AIDS pandemic. HIVMA strongly supports the development of public policies based on science. It is for this reason that we believe the criteria used by the Food and Drug Administration (FDA) to exclude potential blood donors should be revised to reflect the reliability of current blood testing technology and scientific knowledge regarding HIV transmission.

In 2002, the Food and Drug Administration approved the Nucleic Acid Amplification Test (NAT) to screen whole blood donors for the HIV-1 virus and the hepatitis C virus (HCV). The NAT reduces the window period for detecting HIV-1 to 11 days and the window period for detecting HCV to 10 days and is now widely used by blood donation centers. A study conducted from 1999 to 2002 among all major blood donation laboratories confirmed that the implementation of the NAT has improved the safety of the blood supply.<sup>1</sup>

The accuracy and reliability of the NAT coupled with the fact that the HIV virus is transmitted through behaviors and not by sexual orientation<sup>2</sup> call for significant revisions to the current donor screening guidelines. It is discriminatory and unnecessary to continue to exclude any man who has had sex with another man since 1977 from donating blood. Furthermore, the wholesale exclusion of anyone who has ever used a needle to take drugs or steroids is similarly problematic.

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. To err on the side of caution, the period of risky activity might be defined as the previous six months.

<sup>1</sup> Stramer SL, Glynn SA, Kleinman SH, et al. Detection of HIV-1 and HCV infections among antibody-negative blood donors by nucleic acid-amplification testing. *N Engl J Med* 2004;351:760-8.

<sup>2</sup> The Centers for Disease Control and Prevention (CDC) estimates that 33 percent of new HIV infections are transmitted through heterosexual sex, 25 percent through injection drug use and 42 percent through homosexual sex. Source: CDC. HIV/AIDS Update: A Glance at the HIV epidemic. Accessed online <http://www.cdc.gov/hiv/stats/hasrsupp.htm> on August 4, 2004.