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making the case for equality

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BY FACSIMILE TRANSMISSION AND MAIL

Jerry A. Holmberg, PhD
Executive Secretary
Advisory Committee on Blood Safety and Availability
Office of Public Health and Science
Department of Health and Human Services
1101 Wootton Parkway, Suite 250
Rockville, MD 20852
Fax: 240-453-8456

Re: HHS Advisory Committee on Blood Safety and Availability
Meeting re FDA's Current MSM Deferral Policy

Dear Dr. Holmberg:

Lambda Legal is pleased to learn that the Health and Human Services Advisory Committee on Blood Safety and Availability (ACBSA) plans to review the longstanding Food and Drug Administration (FDA) policy permanently excluding from blood donation any man who has had sex with another man since 1977. That policy is not scientifically justified, is discriminatory and promotes misunderstanding about gay and bisexual men and the transmission of HIV.

Lambda Legal is a national organization committed to achieving full recognition of the civil rights of lesbians, gay men, bisexuals, transgender people and those living with HIV through impact litigation, education and public policy work. Lambda Legal has represented the interests of people living with HIV since the beginning of the epidemic, and our work has ensured access to treatment, promoted effective prevention policies, and helped combat discrimination, bias and stigma. Headquartered in New York City and with regional offices in Atlanta, Chicago, Dallas and Los Angeles, we have advocated on behalf of people living with HIV throughout the United States.

Lambda Legal shares the government's concern about ensuring that the blood supply is safe and that screening is accurate and appropriate. To ensure that goal is achieved, donor suitability and deferral rules need to be based on sound science, taking into account current medical knowledge and testing technology.

As noted in your published announcement for the upcoming ACBSA meeting on this subject, even with the highly sensitive screening tests used currently, some deferral period is needed for donors with high-risk exposure due to the risk of false negatives during the

window period between infection and possible detection via screening. 75 Fed. Reg. 28619 (May 21, 2010). However, there is a huge gap between a scientifically defendable deferral period and the current policy banning donation by any man who has had sex with another man even one time since 1977. Since the early 1980's (when the FDA first excluded men who have had sex with men as donors based on risk of transmitting HIV) and 1992 (when the FDA issued the exclusion recommendation in its current form), very significant advances have been made in the sensitivity and accuracy of tests used to screen blood donors for HIV. These advances have dramatically reduced the risk of a person testing negative when he or she actually has HIV. The antibody test will detect antibodies of HIV within two to eight weeks of infection for most people, although in rare cases it may take up to six months for antibodies to be produced.[1] The Nucleic Acid Test (NAT) – now commonly used to test donated blood – has a much shorter window period for detecting HIV, typically detecting HIV within nine to eleven days after infection.[2] In light of the reliability of current blood testing technology and scientific knowledge regarding HIV transmission, a lifetime ban on donation for any man who has had sex with another man since 1977 is not scientifically justifiable.

Both the lack of scientific justification for the current policy and its discriminatory nature are shown by the policy's failure to distinguish between higher and lower risk sexual behaviors. For example, the FDA has concluded that someone who had unprotected sex with a person *known* to be HIV-positive can safely donate a year after that contact.[3] In contrast, a man who had sex with another man at any time in the past *thirty-three years*, *regardless* of his sex

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[1] *See, e.g.*, Centers for Disease Control and Prevention (CDC), *Questions and Answers: How Long After a Possible Exposure Should I Wait to Get Tested for HIV?*, http://www.cdc.gov/hiv/topics/testing/resources/qa/index.htm (last visited June 4, 2010).

[2] *See, e.g.*, *id*; CDC, *Questions and Answers: How Safe is the Blood Supply in the U.S.?*, http://www.cdc.gov/hiv/resources/qa/qa15.htm (last visited June 4, 2010); FDA, *Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays*, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/ucm080466.htm (last visited June 4, 2010).

[3] *See, e.g.*, FDA, *Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components* (2006), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm062915.pdf; AABB Donor History Task Force, *Blood Donor History Questionnaire Version 1.1: Full Length Donor History Questionnaire* (2005), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/UCM164190.pdf; American Red Cross, *Eligibility Criteria by Alphabetical Listing*, http://www.redcrossblood.org/donating-blood/eligibility-requirements/eligibility-criteria-alphabetical-listing (last visited June 4, 2010).

partner's HIV status, is prohibited from donating blood.[4] Moreover, that permanent deferral from donation does not take into account other factors, such as whether the man has been in a long-term monogamous relationship or whether the man has engaged only in low-risk sexual behaviors.[5] This differential treatment of men who have had sex with men also fails to reflect that heterosexuals are increasingly at risk for HIV infection. The Centers for Disease Control and Prevention (CDC) estimated that thirty-one percent of new incidences of HIV in the U.S. in 2006 resulted from "high-risk heterosexual contact."[6] And as of 2006, in the U.S. twenty-eight percent of the people – and seventy-two percent of the women – living with HIV were infected through high-risk heterosexual contact.[7] The current ban on men who have had sex with men clearly screens men out based on sexual orientation, *not* on risk of HIV transmission.

The FDA's perpetuation of the outdated ban on donation by men who have had sex with other men is not only unjustified, it is harmful. This policy unnecessarily prohibits many safe potential donors from contributing to the blood supply.[8] In addition, it contributes to ignorance in the general population about how HIV is transmitted and what behaviors put one at risk of contracting or transmitting HIV. Screening on this basis reinforces a false and very damaging impression that every man who has sex with another man potentially has HIV – irrespective of such relevant factors as when that man last had sex with another man, whether the man engaged in safe sexual practices and the serostatus of the man's sexual partner. The prevalence of such stigmatizing perceptions was demonstrated in a national telephone survey conducted in 1998 and 1999, which found that thirty-three percent of male

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[4] Lifetime exclusions also are imposed on intravenous drug users and people who have engaged in sex for money or drugs, yet persons who have had sex with someone engaging in those risk behaviors are barred from donating only for 12 months. *See, e.g.*, American Red Cross, *supra* note 3.
[5] Concern about unreliable responses to a donor questionnaire, *see* 75 Fed. Reg. 28619, also does not justify the current policy. In fact, it makes no sense to assume that more accurate answers will be obtained in response to a question embodying an excessively restrictive policy than to a question (or questions) which embody a policy based on scientific understanding of risks.
[6] CDC, *HIV Incidence*, http://www.cdc.gov/hiv/topics/surveillance/incidence.htm (last visited June 4, 2010).
[7] CDC, *What Does the Article Show Us in Terms of Distribution of Transmission Categories?*, http://www.cdc.gov/hiv/topics/surveillance/resources/qa/prevalence.htm (last visited June 4, 2010).
[8] The Williams Institute has just released an analysis of the possible impacts of lifting or modifying the ban on blood donation by men who have had sex with men. Naomi G. Goldberg & Gary J. Gates, *Effects of Lifting Blood and Organ Donation Bans on Men Who Have Sex With Men*, The Williams Institute (2010), *available at* http://www.law.ucla.edu/WilliamsInstitute/publications/Formatted MSM_Goldberg_Gates.pdf. The researchers estimated that "53,269 additional men are likely to donate 89,716 pints each year" if the donor criteria are changed to allow donations if a man has not had sex with another man during the past year (comparable to, for example, the current restriction on donations by a person who has had sex with someone known to have HIV). *Id.* at 2 (and also providing estimates of the impact of completely lifting the ban and of changing to a five-year deferral period).

respondents and forty-six percent of female respondents incorrectly believed that HIV transmission could occur through unprotected sex between two *uninfected* men.[9] By continuing the prohibition on blood donations by any man who has had sex with another man since 1977, the blood donation screening policy perpetuates that misperception. And by failing to consistently and accurately reflect what constitutes high-risk behavior, the blood screening process misses an opportunity to educate the population about HIV transmission and the differences between low-risk and high-risk behaviors.

For reasons including some of those set forth above, medical organizations and organizations specifically dedicated to ensuring a safe supply of blood for transfusion in this country support changing the donor eligibility criteria based on social behaviors. The HIV Medicine Association recommends that potential donors be excluded based on possible HIV risk from sexual contact only if a person has engaged in unprotected sex with a partner of unknown HIV status and suggests that the deferral period be six months.[10] In a joint statement to the Blood Products Advisory Committee on March 9, 2006, the American Red Cross, America's Blood Centers and AABB (formerly, the American Association of Blood Banks), called on the FDA to revise its criteria, stating that the current policy is "medically and scientifically unwarranted."[11] Those organizations recommended that "deferral criteria be modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections."[12]

Criteria for excluding blood donors based on social behaviors must reflect current medical understanding of HIV infection and the current ability to ensure the safety of the blood supply. Those criteria should focus on risk behavior and any deferral periods should consistently focus on whether a potential donor actually has engaged in risk behavior within an appropriate time period. A permanent ban on donating if a man has engaged in sex with another man in the past thirty-three years is not medically justified and should not be

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[9] Gregory M. Herek *et al.*, *When Sex Equals AIDS: Symbolic Stigma and Heterosexual Adults' Inaccurate Beliefs about Sexual Transmission of AIDS*, 52 Social Problems 15, 28 (2005).
[10] HIV Medicine Association, *Policy Statement on Donor Screening Guidelines for Blood Donation* (Sept. 30, 2004), *available at* https://www.hivma.org/Content.aspx?id=2788.
[11] Steven Kleinman, *Joint Statement Before BPAC on Behavior-Based Blood Donors Deferrals in the Era of Nucleic Acid Testing (NAT)* (Mar. 9, 2006), *available at* http://www.aabb.org/pressroom/statements/Pages/bpacdefernat030906.aspx.
[12] *Id.* at 9 (and noting, *inter alia*, that "[p]resenting blood donors judged to be at risk of exposure via heterosexual routes are deferred for one year while men who have had sex with another man even once since 1977 are permanently deferred.").

perpetuated. Lambda Legal urges this Committee to work to reform blood donation policy – ending the stigmatizing message sent by the current policy and allowing gay and bisexual men at low or no risk for HIV to donate blood.

Sincerely,

Bebe J. Anderson
HIV Project Director