



Lambda Legal
making the case for equality

August 4, 2008

BY FACSIMILE TRANSMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
Via fax: 301-827-6870

Re: Food and Drug Administration, HHS – Docket No. 2006N-0221:
Comments on “Requirements for Human Blood and Blood Components
Intended for Transfusion or for Further Manufacturing Use”

To the Food and Drug Administration:

Set forth below are comments on the Proposed Rule on “Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use,” published at 72 Fed. Reg. 63416 (Nov. 8, 2007).¹ Specifically, these comments address the need to revise the requirement with reference to screening for donor suitability and deferral based on social behaviors that currently excludes every man who has had sex with a man since 1977, regardless of risk behaviors.

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 FDA’s concern about ensuring that the blood supply is safe and that screening is accurate and appropriate. To ensure that goal is achieved, the agency needs to base donor suitability and deferral rules on sound science, taking into account current medical knowledge and testing technology. Unfortunately, it appears that the Proposed Rule may perpetuate the longstanding ban against blood donation by men who have had sex with men since 1977.

¹ Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, 72 Fed. Reg. 63416 (Nov. 8, 2007) (to be codified at 21 C.F.R. pts. 606, 610, 630, 640, 660, 820, & 1270). By notice dated January 11, 2008, the deadline for submission of comments was extended to August 4, 2008. 73 Fed. Reg. 1983 (Jan. 11, 2008).

Among the factors (set forth in proposed regulation 630.10(f)) that will render a donor “ineligible because of increased risk for, or evidence of, a relevant transfusion-transmitted infection” – such as HIV – is “[s]ocial behaviors associated with relevant transfusion-transmitted infections.” 72 Fed. Reg. at 63440. The Proposed Rule does not identify what “social behaviors” will preclude donation. *Id.* The agency states in its Summary of the Proposed Rules that, to assist it with providing guidance documents, it intends to hold workshops and public meetings and to provide the opportunity for public comments concerning what specific social behaviors should form a basis for ineligibility. *See id.* at 63425. We welcome those future opportunities for input on this important issue.

However, other language in the Summary of the Proposed Rule appears to indicate that the FDA intends to continue its policy regarding men who have had sex with men. The Summary states that “draft guidances” included in specified documents – including the FDA’s April 23, 1992 recommendations on preventing HIV transmission by blood and blood products² – “when finalized, will represent FDA’s current thinking on those topics.” 72 Fed. Reg. at 63424. The recommendations in the 1992 document currently form the basis for excluding donors and, as noted later in the Summary, social behaviors that currently preclude donation specifically include “men who have had sex with another man even one time since 1977.” *Id.* at 63425.³

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 revised its criteria – very significant advances have been made in the sensitivity and accuracy of tests used to screen whole blood donors for HIV. In particular, the Nucleic Acid Test (NAT) – approved for use by the FDA in 2002⁴ – has reduced the window period for detecting HIV (thus dramatically reducing the risk of a person testing negative, even when he or she is actually HIV positive). 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 medically justifiable.

The bans’ current lack of scientific basis is apparent from the fact that FDA has concluded that someone who had sex with a person *known* to be HIV-positive can safely donate a year after that contact.⁵ Yet a man who had sex with another man at any time in the past *thirty-one*

² Food and Drug Administration (FDA), *Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products* (April 23, 1992), available at www.fda.gov/oashi/aids/1992policy.html.

³ *See also* FDA, *supra* note 2.

⁴ 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)* (Feb. 2, 2002), <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01140.html> (last visited Aug. 4, 2008).

⁵ *See* FDA, *supra* note 2.

years, regardless of his sex partner's HIV status, is prohibited from donating blood.⁶ 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.

Accordingly, 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 within the previous six months.⁷ 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."⁸ 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."⁹

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. 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 perpetuates 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 damaging and false perceptions was demonstrated by the findings of a 2005 national study, in which 33% of male respondents and 46% of female respondents incorrectly believed that HIV transmission could occur through unprotected

⁶ 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. FDA, *supra* note 2.

⁷ HIV Medicine Association (HIVMA), *Policy Statement on Donor Screening Guidelines for Blood Donation* (Sept. 30, 2004), available at <http://www.hivma.org/Content.aspx?id=2788>.

⁸ Kleinman, S., Statement at Blood Products Advisory Committee: Behavior-Based Blood Donors Deferrals in the Era of Nucleic Acid Testing (NAT) (Mar. 9, 2006), http://www.aabb.org/Content/Members_Area/Members_Area_Regulatory/Donor_Suitability/bpacdefernat030906.htm, (last visited Aug. 4, 2008).

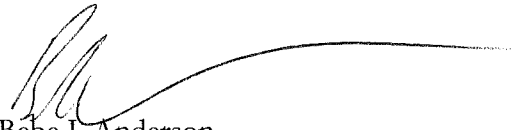
⁹ Kleinman, *supra* note 8 (and noting, *inter alia*, that "[p]resenting blood donors judged to be at risk of exposure via heterosexual routes are deferred for one year while men who have had sex with another man even once since 1977 are permanently deferred."); see also Centers for Disease Control and Prevention (CDC), *HIV Incidence* (Aug. 3, 2008), <http://www.cdc.gov/hiv/topics/surveillance/incidence.htm> (last visited Aug. 4, 2008) (reporting new estimates of HIV incidence in United States, including estimate that 31% of new incidences in 2006 resulted from "high-risk heterosexual contact").

sex between two *uninfected* men.¹⁰ By precluding blood donations by any man who has had sex since 1977 with another man, the FDA no doubt contributes to that misperception.

Criteria for excluding blood donors based on social behaviors must reflect current medical understanding and the current ability to ensure the safety of the blood supply. A permanent ban on donating if a man has engaged in sex with another man in the past thirty-one years is not medically justified and should not be perpetuated. Along the same lines, the educational materials developed for review by potential donors¹¹ need to accurately discuss the current understanding of the behaviors that put a person at risk of contracting HIV.

We believe that the FDA should revise its specific guidance on the use of “social behaviors” as a basis for donor ineligibility in line with the position of the HIV Medicine Association. We request that the agency draft the Final Rule so as to make clear that the Final Rule is not recommending continuation of the ban on donation by men who have had sex with other men since 1977. Finally, we request that the Comments in the Final Rule regarding the development of new guidance on donor eligibility criteria note the positions of the medical and blood donation organizations referenced above and state FDA’s intention to develop new guidance that will focus consistently on whether a potential donor actually has engaged in risk behavior within an appropriate time period.

Sincerely,



Bebe J. Anderson

HIV Project Director

¹⁰ Herek, G. *et al.*, “When Sex Equals AIDS: Symbolic Stigma and Heterosexual Adults’ Inaccurate Beliefs about Sexual Transmission of AIDS,” *Social Problems*, 52(1), 15-37 (2005).

¹¹ See 72 Fed. Reg. at 63423, 63439 (Proposed Rule 630.10(b)).