

End Discrimination against Gay and Bisexual Blood Donors

Issue

The Food and Drug Administration's ("FDA") lifetime deferral policy that prohibits men who have had sex with men ("MSM") from donating blood is discriminatory and medically unnecessary.

Short Answer

The FDA's Center for Biologics Evaluation and Research ("CBER") should abolish its blood donation deferral policy for low-risk MSM and should reduce the deferral period to twelve months for high-risk MSM.

Background

Since 1977, the FDA has banned men from donating blood if they have, even once, had sex with another man.¹ The FDA implemented this lifetime deferral policy in 1983 to protect the nation's blood supply from HIV, which at the time was more prevalent among MSM than any other group.² At the time, the medical and scientific community agreed that the lifetime deferral for MSM blood donors was a necessary precaution: although early HIV tests were highly accurate, their long window periods for detection increased the risk of blood infected with undetected HIV entering the blood supply.³ New HIV tests, however, have a much shorter window period and are more accurate than early tests. The Nucleic Acid Test ("NAT") system, which is used to test most blood donations in the United States, has an average window period of 12 days.⁴ The NAT system can detect more infectious donations than other tests because it detects viral genes themselves, rather than antibodies or viral proteins, thus allowing the NAT system to detect infection earlier.⁵

The FDA's lifetime deferral policy discriminates against MSM and is medically unnecessary in light of the high accuracy and shortened window periods of the NAT system. By failing to revise the lifetime deferral policy, the FDA overlooks the improved accuracy of the NAT system and assumes that all sexual activity among gay and bisexual men is at high risk for HIV. Although blood centers should screen potential donors and exclude individuals who are at a high risk for contracting HIV, FDA policy should not bar individuals who engage in low-risk behaviors from donating. Men who

¹ U.S. FOOD AND DRUG ADMIN., *FDA Policy on Blood Donations from Men Who Have Sex with Other Men* (May 23, 2007), <http://www.fda.gov/cber/faq/msmdonor.htm>. The FDA states its policy as: "Men who have had sex with other men, at any time since 1977 (the beginning of the AIDS epidemic in the United States) are currently deferred as blood donors. This is because MSM are, as a group, at increased risk for HIV, hepatitis B and certain other infections that can be transmitted by transfusion."

² Question 34 of the FDA-approved Donor History Questionnaire, <http://www.fda.gov/cber/dhq/dhq.htm>, asks male donors: "From 1977 to the present, have you had sexual contact with another male, even once?" Male donors who reply "yes" are indefinitely deferred from donating blood.

³ The window period is the time from infection until a test can detect any change.

⁴ U.S. FOOD AND DRUG ADMIN., *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. 28, 2002), <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01140.html>. Early antibody HIV tests had an average window period of 22 days, and antigen tests have an average window period of 16 days.

⁵ *Id.*

consistently use condoms or are in monogamous relationships, for example, are at a much lower risk of contracting HIV than are MSM with high-risk behaviors. The FDA treats individuals who are not MSM according to their risk levels and should make its policy fair and consistent by treating all potential donors according to risk levels. The FDA's current deferral policy not only discriminates against low-risk MSM, but it also harms the general public by preventing low-risk individuals from donating healthy blood to a system that faces frequent blood shortages.⁶

The lifetime deferral policy is no longer necessary to maintain a safe blood supply. The American Red Cross, America's Blood Centers, and AABB (formerly American Association of Blood Banks) recommend that the deferral period for MSM blood donors be reduced to twelve months.⁷ A deferral of twelve months would make the deferral period consistent with the deferral period for other potentially high-risk behaviors and would improve the consistency of donor screening questions.⁸ A twelve-month deferral period would also direct donors to focus on recent risk behaviors and would allow them better recall for answers to screening questions. Blood is currently tested in duplicate processes, with both NAT and serologic methods, allowing detection of HIV-infected donors between ten and twenty-one days after exposure.⁹ This testing process makes a lifetime deferral unnecessary because the critical period for HIV high-risk behavior screening is the three weeks immediately preceding donation.¹⁰ As a result of improved testing, countries other than the U.S. have begun to review and revise lifetime deferral policies for MSM blood donors. In 2007, Russia changed its policy to a five-year deferral,¹¹ and Canada is currently reviewing its deferral policy.¹² Additionally, U.S. federal regulations have already removed the lifetime deferral for MSM tissue and organ donors. Male tissue and organ donors who have had sex with another man in the preceding five years are deferred from donating.¹³

Recommendation

⁶ Some local governments and universities have canceled blood drives in opposition to the lifetime deferral policy, or have refused to follow the FDA lifetime deferral policy. See *California County Board of Supervisors Votes To Oppose FDA Policy Barring MSM From Donating Blood*, MED. NEWS TODAY, Feb. 29, 2008, <http://www.medicalnewstoday.com/articles98995.php>.

⁷ AABB, AMERICA'S BLOOD CTNS., & AMERICAN RED CROSS, *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.

⁸ The FDA Questionnaire asks donors if, in the past 12 months, they have had a blood transfusion, had an organ or tissue transplant, come in contact with someone else's blood, had sexual contact with anyone who has HIV/AIDS, or had a tattoo. The FDA Questionnaire asks female donors if, in the past 12 months, they have had sex with an MSM.

⁹ AABB *et al.*, *supra* note 7.

¹⁰ AABB *et al.*, *supra* note 7.

¹¹ Russia previously had a lifetime deferral policy for men who have had sex with men since 1977.

¹² CANADIAN BLOOD SERVICES, *Public Statement Update on Review of MSM Deferral Policy* (Mar. 16, 2007), http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/page/E_Public-Statement-on-MSM-Policy-Status?OpenDocument&CloseMenu.

¹³ FDA CTR. FOR BIOLOGICS EVALUATION AND RESEARCH, ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS), § 1271.75 (Aug. 2007), <http://www.fda.gov/cber/gdlns/tissdonor.htm>; U.S. CTR. FOR DISEASE CONTROL AND PREVENTION, GUIDELINES FOR PREVENTING TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS THROUGH TRANSPLANTATION OF HUMAN TISSUE AND ORGANS, 43 (RR-8) MORBIDITY AND MORTALITY WEEKLY REP. 1 (May 20, 1994), <http://wonder.cdc.gov/wonder/prevguid/m0031670/M0031670.asp>. The FDA supports the five-year deferral for MSM organ and tissue donors. See Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,806 (May 25, 2004).

The Commissioner of Food and Drugs (“Commissioner”), at the direction of the Secretary of Department of Health and Human Services (“DHHS”),¹⁴ should direct the FDA’s Center for Biologics Evaluation and Research (“CBER”) to change the FDA’s MSM deferral policy for blood donation to distinguish MSM who engage in high-risk behaviors from MSM at low-risk of acquiring HIV. For high-risk MSM, CBER should replace the lifetime deferral on blood donation with a twelve-month deferral from last sexual contact. For low-risk MSM, CBER should abolish the deferral policy and allow blood donations from low-risk MSM just as it would allow blood donations from other low-risk individuals.

Authority

Under the Federal Food, Drug, and Cosmetic Act, the Commissioner is responsible for “promot[ing] the public health by taking appropriate action on the marketing of regulated products,”¹⁵ including blood, which is classified as both a drug under the Federal Food, Drug, and Cosmetic Act¹⁶ and as a biological product under the Public Health Service Act.¹⁷ Although the current MSM deferral policy as drafted by CBER has been followed by the Commissioner upon recommendation by the Blood Products Advisory Committee (“BPAC”),¹⁸ the Commissioner is in no way compelled to follow its recommendations as BPAC is only an advisory committee.¹⁹

¹⁴ See 21 U.S.C. § 393(d)(2)(A) (stating that the Secretary of DHHS shall be responsible...for...establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration”).

¹⁵ *Id.* at § 393(b)(1) (2008).

¹⁶ *Id.* at § 321(g)(1)(B).

¹⁷ 42 U.S.C. § 262(j) (2008).

¹⁸ BLOOD PRODUCTS ADVISORY COMM., Meeting Transcript (Mar. 9, 2006), <http://www.fda.gov/ohrms/dockets/ac/06/transcripts/2006-4206r1.pdf>.

¹⁹ See 5 U.S.C. app. § 2(b)(6) (2008).