



June 11, 2012

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RE: “HHS-OPHS-2012-0003” Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Had Sex with Other Men (MSM)

On behalf of the American Civil Liberties Union (ACLU), a non-partisan organization with more than a half million members, countless additional activists and supporters, and fifty-three affiliates nationwide, we are writing to offer our comments on the Request for Information (RFI) published in the Federal Register on Tuesday, March 13, 2012¹ on the design of a pilot operational study (or studies) on the alternative donor deferral criteria that would permit blood and plasma donations by men who have had sex with other men since 1977.

We would like to begin by first thanking the U.S. Department of Health and Human Services (HHS) for the work that has taken place so far regarding a reevaluation of the lifetime blood donation ban for gay and bisexual men. This includes the decision by the Advisory Committee on Blood Safety and Availability in June 2010 to label the current policy as “suboptimal,” stressing the need for targeted research studies that might support a safe alternative policy, as well as the decision by the Assistant Secretary for Health to charge the relevant agencies with developing a plan of action to allow for further review and reevaluation of the ban. The ACLU has long urged that decisions on this matter be based on scientific evidence, rather than relying on outdated, discriminatory stereotypes and assumptions.

¹ Request for Information (RFI) on Design of a Pilot Operational Study To Assess Alternative Blood Donor Deferral Criteria for Men Who Have Had Sex With Other Men (MSM), 77 Fed. Reg. 14, 801 (Dep’t of Health and Human Services March 13, 2012) (notice).

As HHS moves forward with considering the design, logistics and feasibility of a pilot operational study (or studies), HHS must ensure that behaviors that pose similar risks for HIV transmission and other transfusion-transmissible infections are treated alike. To the extent that the available evidence suggests that either a shorter deferral period or an eligibility policy that is based on an assessment of individual risk would not pose a greater risk to the nation's blood supply than the more nuanced eligibility policies already in existence for other demographic groups, treating gay and bisexual men differently would pose serious constitutional concerns. Accordingly, any pilot studies should be designed to ensure that they are measuring comparable risks.

Gay and bisexual men, intravenous drug users, people who have had sex for money, and people who have tested positive for HIV disease are presently the *only* groups of people banned from donating blood. The current, "suboptimal" policy excludes all gay and bisexual men regardless of their individual sexual histories or HIV risk. Other individuals who are also at increased risk for HIV disease, however, including people who have heterosexual sex with someone who they know to have HIV, or people who have had sex with a commercial sex worker, are prevented from donating blood for only a year. Because the current policy establishes different standards for behavior that poses similar (or greater) risk of HIV transmission, it appropriately has been criticized as stigmatizing and discriminatory to gay and bisexual men.

The guarantee of equal protection codified in the Fifth and Fourteenth Amendments to the U.S. Constitution "is essentially a direction that all persons similarly situated should be treated alike."² While there is no constitutional right to donate blood, government policy regulating the blood donation field must not discriminate on the basis of sexual orientation by adopting differing standards for conduct that poses similar risks based solely on the identity of those engaging in such conduct. In other words, gay and bisexual men cannot constitutionally be singled out for differential treatment solely because of their sexual relationships.³ Instead, the eligibility standards must reflect current scientific knowledge, and must treat like risks alike.

Further, if the blanket exclusion is not indeed necessary to ensure the safety of the blood supply, a position embraced by organizations including the American Red Cross and the American Association of Blood Banks and America's Blood Centers, important public health reasons support changing the policy. By categorically barring all gay and bisexual men from donating blood, the current policy wrongly signals that – regardless of whether condoms are used consistently, regardless of the number of sexual partners, and regardless of the kind of sexual

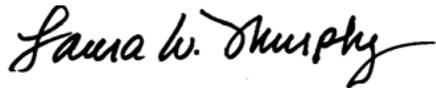
² *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985).

³ See *Romer v. Evans*, 517 U.S. 620 (1996) (striking down a state constitutional amendment that deprived gay, lesbian and bisexual people of protection under state nondiscrimination laws); *Lawrence v. Texas*, 539 U.S. 558 (2003) (striking down Texas law that criminalized same-sex sexual activity because of the burden it imposed on protected liberty and intimate relationships).

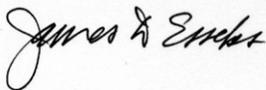
activity engaged in – the mere fact of a man having had any sexual activity ever with another man poses a risk of HIV transmission. An eligibility policy that barred donations from any man who has had sex with another man within the previous year or five years, for example, could raise similar concerns. Suggesting that sexual activity with another man, in and of itself, poses a risk of HIV transmission is stigmatizing, runs contrary to effective HIV prevention education, ignores the need for individualized behavioral risk assessments, and may in fact contribute to an increase in higher risk behavior, as it fails to distinguish between high risk and safer sex practices (e.g., two men who maintain a committed, monogamous relationship).

The Obama administration has made commendable progress in updating policies impacting those living with HIV and AIDS to ensure that they are based on sound science and not discriminatory stereotypes that originated in a time when ignorance and fear about HIV/AIDS, and those living with the disease, ran wild. We are pleased to see a similar approach being taken on this issue. The ACLU urges HHS to apply the principles outlined above as it begins the process of developing the design of a pilot operational study (or studies) on alternative donor deferral criteria. If you have questions, please contact Ian Thompson at (202) 715-0837 or ithompson@dcaclu.org.

Sincerely,



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