

By email to glynnsa@nhlbi.nih.gov
National Heart, Lung, and Blood Institute
Attn: Simone Glynn, Project Officer/ICD Contact
Two Rockledge Center, Suite 9142
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April 23, 2012

**Re: Proposed Collection; Comment Request; Opinions and Perspectives About the Current Blood Donation Policy for Men Who Have Sex With Men
Federal Register Notice Vol. 77, No. 36 (Feb. 23, 2012)**

To the National Heart, Lung and Blood Institute:

Lambda Legal finds it encouraging that the National Institutes of Health (NIH)'s National Heart, Lung and Blood Institute (NHLBI) wants to engage in research that will support a change in the blood donation policy for men who have sex with men (MSM). The current policy is not scientifically justified, is discriminatory and promotes misunderstanding about gay and bisexual men and about the transmission of HIV. However, we believe that the data collection project (the "Project") described above-referenced Announcement the Project is unnecessary and will be of limited, if any, practical utility. Any change in the current MSM blood donation policy should be based on sound science – taking into account current medical knowledge and testing technology – not on the opinions and perspectives of a small fraction of the MSM population that are donating blood in contravention of the current discriminatory policy. But if the Project is going to move forward nonetheless, its scope should be greater than a comparison of the current policy with only one other potential policy. Instead, data should be collected regarding opinions and perspectives about, and intended compliance with, a variety of potential new policies based on current medical knowledge and testing technology, including a policy that would evaluate all potential donors based on their sexual risk behaviors without regard to the sex of either the potential donors or their partners.

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. At the same time, we are aware of and concerned about the current policy's discriminatory exclusion of gay and bisexual men from the donor pool and its effect on the blood supply, as well as the harmful and inaccurate messages sent by that policy. Moreover, over the years, the blood donation standards have been mirrored in other government policies relating to sperm donation, organ donation and transplants. The ramifications have been serious in each of these areas, and the discrimination in these policies is medically and scientifically unjustified but can be life altering or even life threatening. Lambda Legal has fought to secure and protect the rights of our communities in these areas. See, e.g. Dec. 2011 Comments of Lambda Legal and the Gay and Lesbian Medical Association re Proposed Organ Donation Guidelines (available at http://www.lambdalegal.org/in-court/legal-docs/ltr_20111221_organ-transplantation-guideline-comments); Aug. 2004 Comments of Lambda Legal Defense and Education Fund, the Gay and Lesbian Medical

Association, the Human Rights Campaign and the National Center for Lesbian Rights to FDA on Draft Guidance Relating to Sperm Donor Eligibility (available at http://www.lambdalegal.org/in-court/legal-docs/ltr_fda_20040823_draft-guidance-re-sperm-donorspdf). That is why we believe that a change in the current policy should be based on current scientific knowledge and medical testing technologies, with an eye toward altogether eliminating, or at least significantly reducing, any unjustified exclusions. It is possible to maximize blood supply and eliminate discrimination without compromising blood safety. Creating a policy that serves all of these goals should be the priority.

With all of the foregoing in mind, we believe that the Project appears unlikely to yield data that would inform the creation of such a policy. It is already known that the current policy is both discriminatory and perceived to be discriminatory while failing to maximize blood safety by permitting donations from certain high risk heterosexual blood donors, and that changing it is long overdue. See, e.g., Lambda Legal Aug. 2008 Comments to FDA Proposed Rule on Screening Blood Donors Based on HIV Exposure (available at http://www.lambdalegal.org/in-court/legal-docs/ltr_fda_20080804_requirements-human-blood-and-components). Gathering the perspectives and opinions of those against whom the policy discriminates seems unlikely to shed new light. It is also known that a small number of MSM have donated blood in defiance of the current policy. Notably, the information identified in the Announcement shows that the population of MSM is not the only cohort donating in contravention of current policy.¹ Yet the Proposal's stated "third aim" ("to assess motivations for donating in the group of self-identified MSM who are active blood donors in the U.S.") would single out MSM as the only population whose opinions and perspectives are to be gathered, and whose "motivation" for donating blood is to be scrutinized – making it impossible to compare, much less analyze, whether the motives of MSM differ from the motives of others who donate in spite of identifiable risk factors. Once a new policy has been adopted, it may be useful to gather opinions and perspectives that would inform educational and informational strategies to maximize compliance with it. But it seems premature – and, therefore, not a prudent use of limited resources – to gather such data at this point in time, and we respectfully suggest that resources would be better allocated to other projects.

Given, however, the likelihood the Project will move forward despite the concerns voiced above – and our recognition that there may nevertheless be some interest in collecting opinions and perspectives about current blood donation policies and potential changes to the current policy, in order to supplement and more fully inform the decision-making process – we offer the following three modifications that would significantly enhance the utility of the data collected.

First, the Project should gather data concerning policies with different deferral periods, rather than being limited to only two policies – the current policy and one potential policy with a "deferral of a defined shorter duration." Reactions to a new potential policy may vary widely depending on the deferral's duration. For instance, a 12-month deferral period—while a significant improvement over the current policy—is also not justified by current medical knowledge or testing technology, and is, therefore, discriminatory against gay and bisexual men. According to information that has been available for some time, HIV antibody tests will detect antibodies of HIV in most people within two to eight weeks of infection (although in rare cases the "window" period for production of antibodies is six months). See, e.g.,

¹ The 1980s study referenced in the Announcement reported that, of male donors determined to be HIV positive in pre-donation testing, "MSM behavior [was] a risk factor for 56%" – which means that MSM behavior was *not* a risk factor for 44% of male donors testing positive. Presumably, "MSM behavior" was not a risk factor identified for female donors determined to be HIV positive.

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 April 23, 2012). Furthermore, the testing technology continues to improve, becoming more accurate and within shorter time periods. For example, the Nucleic Acid Test (NAT) for HIV—has a much shorter window period for detecting HIV, typically detecting HIV within five to six days of the onset of infection. Given the varying sensitivity of the available tests, it would make most sense to gather opinions about policies with different deferral periods that could be justified by current and reasonably foreseeable science and testing technologies (e.g., 12 months, 6 months, 8 weeks and 2 weeks).

Second, the Project should inquire about potential policies that are not framed solely in terms of deferral periods. Limiting the questions only to potential changes in deferral periods will be of no use in determining whether some other proposed change in policy would be preferable and/or would lead to better compliance. For example, a policy that is behavior-based, without regard to the sex of one's partner, would be more effective and less discriminatory than both the current policy and the hypothetical one-year deferral policy identified in the announcement. A deferral-period policy's singular focus on the sex of one's partner relegates many potential donors to an apparent—and unnecessary—choice between celibacy (even if it is of finite duration) or ineligibility. By contrast, a behavior-based policy that takes into account monogamy, types of sexual activities, and safer-sex practices is preferable, both because it is not discriminatory and because it focuses appropriately on methods of HIV transmission, providing a more accurate assessment of risk and thereby improving blood safety.

Third, the Project should examine the effect of scientifically or medically based justifications on compliance with blood donor restrictions. Any study along these lines should try to ascertain whether intended compliance would improve if respondents were given an effective explanation or justification for each policy or potential policy that is the subject of inquiry. In the United Kingdom study referenced in the Announcement, explaining the justification for the policy was reported to significantly improve the likelihood of compliance. Given the lack of scientifically justifiable data to support the current policy (or, for that matter, a 12-month deferral policy), we believe that collecting data concerning the effect of providing a medical and/or scientific justification for the particular policy change being inquired about could be particularly useful.

We thank you in advance for your careful consideration of the above comments and sincerely hope that they are of use as you consider whether and how to move forward with proposed studies such as those described in the Announcement. If you have any questions about these comments, or if Lambda Legal can be of further assistance in the review and revision process, we would be happy to make ourselves available for further discussion and have included our contact information below.

Sincerely,

Lambda Legal Defense and Education Fund, Inc.



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