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Office of Blood, Organ, and Other Tissue Safety
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Attn: *Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through Solid Organ Transplantation*
Docket No. CDC-2011-0011

December 21, 2011

1600 Clifton Rd, NE.
Mailstop A-07
Atlanta, GA 30329

To the Office of Blood, Organ, and Other Tissue Safety:

Lambda Legal, AIDS United, amfAR, The Foundation for AIDS Research, and The Gay & Lesbian Medical Association are pleased that the Centers for Disease Control and Prevention is engaged in the process of reviewing and revising its guidelines for preventing transmission of human immunodeficiency virus (HIV) through solid organ transplantation (formerly the Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs[1] (hereinafter "1994 Guidelines")). We agree it is important to include considerations related to other blood-borne pathogens, such as hepatitis B virus and hepatitis C virus, and that these guidelines reflect a more contemporary and evidence-based understanding of the actual risks of transmission of blood-borne infections through organ transplantation.

Because these guidelines have not been revised since they were first issued in 1994—and it is unclear when they will next be revisited—we believe it is extremely important that the new guidelines adopted by the Public Health Service incorporate the most current scientific information and rigorous analysis to identify, as precisely as possible, the contours of the category of donors at an "increased risk" of carrying a blood-borne infection. By doing so, the proposed guidelines are more likely to serve the dual goals of minimizing the risk of transmission of blood-borne pathogens and

[1] The 1994 Guidelines also addressed sperm donation, but such donations are currently addressed by other guidelines and recommendations. *See Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)*, available at http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf (last visited December 14, 2011).

maximizing the supply of organs available for transplantation from medically qualified donors throughout our society, including gay men, bisexual men, and transgender people. With these goals in mind, we offer the following comments regarding the Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through Solid Organ Transplantation (hereinafter "Proposed Guidelines").

First and foremost, we applaud the decision of the Expert Panel and Review Committee to standardize the "look-back period"[2] for behavioral factors that lead to placement in the "increased risk" category.[3] Under the 1994 Guidelines, men who have had sex with men ("MSM") in the preceding five years are excluded[4] from donating organs, whereas people who have had sex with a person known to have HIV infection are not excluded from donating, unless that sexual contact occurred within the past twelve months. The longer look-back period for MSM (and others) is not scientifically justified and unfairly deprives people in need of an organ transplant simply because the potential donor is gay or bisexual. Standardizing the look-back period for behavioral risk factors more accurately reflects the reason(s) for placing donors with behavioral risk factors in an "increased risk" category: *i.e.*, that the tests for blood-borne infections—such as HIV, HCV and HBV—may

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[2] Because the Proposed Guidelines do not use a particular term to describe the period of time examined to determine whether it is necessary to categorize a donor's organs as at an "increased risk" of carrying a blood-borne infection based on behavioral risk factors, for the sake of convenience and clarity, we have adopted the term "look-back period" in these comments. (This seems more appropriate to us than the term "deferral period" used in the related contexts of sperm or blood donation, primarily because many organ donors are deceased and, therefore, it is not possible to "defer" donation.)

[3] Though it became clear upon closer review, it was not readily apparent that this indeed was a change the drafters were recommending. The Proposed Guidelines are arranged in a manner that is less than conducive to a clear understanding, and we suggest restructuring for clarity in the final guidelines. For example, describing Section II as a "Summary of Recommendations" is misleading, when Section II is in fact all of the recommendations set forth in full. As another example, we suggest that any table (*e.g.*, Table 3) should be set forth immediately after it is first referenced in the recommendations, and that subsequent references should clearly identify where that table may readily be found within what is a very lengthy document. Furthermore, the change to a standardized look-back period seems significant enough that it should be mentioned in the "Executive Summary." We have not set forth every potential change that we think could make the document easier to comprehend and use, but believe that a review for clarity and ease of use would be beneficial.

[4] Under the 1994 Guidelines, people are "excluded" from donating "unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease," in which case informed consent regarding the possibility of HIV transmission is to be obtained from the recipient. Lambda Legal approves of replacement of the categorical and exclusionary language in favor of the Proposed Guidelines recognition that no organ transplantation is without risk of donor-derived infection ("Organ transplantation always carries a risk of donor-derived disease transmission. Thus, donors without identified risk factors are not presumed to be risk-free, but rather are differentiated from donors with risk factors [*i.e.*, "average risk" donors vs. "increased risk" donors] in that the former possess no *known* serological or historical characteristics that indicate elevated risk." Proposed Guidelines, p. 85). We also approve of the Proposed Guidelines' recognition that ultimately the decision regarding the degree of acceptable risk must be placed in the hands of the organ recipient, in consultation with his or her healthcare provider.

provide false-negative results for individuals who have only recently acquired such an infection. The undersigned strongly commend standardization of the look-back period, because it is more rooted in the science of transmission, eliminates the disparity in the manner in which various behavioral risk factors are addressed, and dramatically reduces the unnecessarily stigmatizing message that the longer look-back period sent about gay and bisexual men, among others.

On the other hand, we question why a look-back period of twelve (12) months was selected by the drafters of the Proposed Guidelines. In the Proposed Guidelines, there is no explanation as to why a 12-month time frame is examined when it appears that a shorter look-back for behavioral risks would reap the same benefits in terms of avoiding transmitted infections, while significantly increasing the number of donors whose risk is categorized as "average." Because all individuals donating organs are to be tested for the three blood-borne infections addressed by the Proposed Guidelines (HIV, HBV, and HCV) as close to the time of donation as possible (*see* Proposed Guidelines at p. 12),[5] the look-back period should be contingent upon the sensitivity of the tests for detecting such infections. In other words, it does not matter whether someone engaged in behavior that potentially may have exposed them to a blood-borne pathogen seven (or more) months ago, if—as is currently the case—the immunoassays to be conducted near the time of donation are able to detect an infection that has been in the person's body for at least six months.[6] Because neither the Proposed Guidelines nor their supplemental materials include evidence that tests for HCV or HBV require a period of more than six months to detect these infections, it seems that use of a longer look-back period will unnecessarily deprive potential recipients of much-needed organ transplants. In these and future guidelines, the drafters should explain the reasons justifying the length of the look-back period they are recommending.

It also remains problematic that such a broad range of actual risk is included within the "increased risk" category, and that there is no meaningful way to distinguish between relatively low-risk sexual contact (*e.g.*, oral sex or sex with a condom) and sexual contacts involving greater risk. We recognize

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[5] Failure to obtain such test results prior to transplantation allows for transplantation only "in situations of life-threatening illness where benefits of transplantation outweigh potential risks of infection transmission." See Proposed Guidelines, p. 14 ("Donor Screening," Recommendation 8).

[6] Indeed, according to previously-available information, for most people the HIV antibody test will detect antibodies of HIV within two to eight weeks of infection—although in rare cases the "window" period for production of antibodies is six months. *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/topicqs/testing/resources/qa/index.htm (last visited December 14, 2011). Furthermore, the Nucleic Acid Test (NAT) for HIV—recommended under the Proposed Guidelines (*see* Page 12-13)—has a much shorter window period for detecting HIV, typically detecting HIV within five to six days of the onset of viremia. *See* Proposed Guidelines, at 23. Given the varying sensitivity of the available tests, it would make most sense to have the recommendation regarding placing an individual's organs in the "increased risk" category contingent upon the sensitivity of the tests used at the particular facility that is harvesting the organ.

the potential difficulty of collecting detailed and specific information regarding the sex lives of potential organ donors, particularly for deceased organ donors (*i.e.*, when the information is being gathered from a third party). But the current and Proposed Guidelines' singular focus on the identity of one's partner relegates many potential donors to an apparent—and unnecessary—choice between celibacy or exclusion from consideration as a donor. Therefore, we suggest that a mechanism be considered for incorporating these mitigating factors into the risk assessment for living donors and/or when such information can readily be obtained with respect to deceased donors. In fact, given what is known about the relative risks of certain types of sexual contact and the effectiveness of condoms in preventing sexual transmission,[7] the Review Committee should consider whether particular information about risk mitigation might appropriately remove the potential donor from the "increased risk" category, thereby saving lives by increasing the availability of organs suitable for transplant.

We also laud the drafters for recognizing the complex and particularized nature of assessing the relative risks (and benefits), the difficulties of communicating those risks, and the importance of each organ recipient's autonomy in determining the level of risk with which s/he is comfortable, given the potential benefits. That said, more must be done to provide organ recipients with meaningful information regarding the relative risks associated with the broad range of behaviors included in the "increased risk" category, because those risks vary widely. Recognizing the invasion of donor privacy—as well as the possibility of potential recipient bias or confusion—that flows from sharing very detailed and specific information regarding the sexual relationships and other behavioral risks of organ donors, we endorse the suggestion that a donor risk index be developed to provide potential recipients with a tool for quantitatively evaluating risk. *See* Proposed Guidelines (EO1.B.), at 88 ("Consider development and evaluation of a relative or comparative risk-based quantitative process, such as a donor risk index, to allow a patient to accept or reject a donor based on level of risk for transmitting HIV, HBV, or HCV."). The undersigned see great value in a tool that would allow relevant, useful information regarding risk to be communicated to a potential recipient without discussion of the specific behaviors identified as risk factors for the donor in question.

We are, however, troubled by proposed guidance contained in the section regarding "Donor Risk Assessment." As currently drafted, Recommendation No. 3 under "Donor Risk Assessment" states, "For prospective living donors with a history of behaviors associated with an increased risk of

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[7] *See, e.g., Condoms and STDs: Fact Sheet for Public Health Personnel* http://www.cdc.gov/condomeffectiveness/latex.htm (last visited December 14, 2011) ("The body of research on the effectiveness of latex condoms in preventing sexual transmission of HIV is both comprehensive and conclusive. The ability of latex condoms to prevent transmission of HIV has been scientifically established in 'real-life' studies of sexually active couples as well as in laboratory studies."); *Sexual Risk Factors*, http://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/sexual-risk-factors/ (last visited Dec. 14, 2011) (discussing the widely varying degrees of risk of HIV transmission involved in different sexual activities).

acquiring HIV, HBV, or HCV identified during evaluation, individualized counseling and a detailed discussion of specific strategies to prevent exposure to these viruses should occur; *however, in most circumstances a discussion of strategies to avoid these behaviors should be provided.* (Refer to *Table 3* for risk factors.)" *See* Proposed Guidelines, p. 12 (emphasis added). Though likely an oversight, this recommendation advises providers to counsel prospective living donors to avoid having any of the sexual contacts described in Table 3, which includes multiple types of normal, healthy—and constitutionally-protected—sexual activity, including sex between two men.[8] While a detailed discussion of specific strategies to avoid exposure to sexually transmitted infections while engaging in these sexual activities is completely appropriate, it is entirely inappropriate to advise people to "avoid these behaviors" altogether (by, for example, celibacy). The undersigned request that this recommendation be modified to reflect the important distinction between activities that are completely legal and perfectly healthy and activities that a person may legitimately be counseled to avoid altogether.

Finally, we commend the Review Committee for suggesting that research be conducted regarding organ donations from HIV-positive individuals to other HIV-positive individuals.[9] There is good reason to believe that the organs of HIV-positive individuals, which are currently ineligible for harvesting, could be used to save and/or prolong the lives of other HIV-positive people with minimal risk of such transplantations harming the recipients.[10] Given the increasing lifespan of people with HIV—as well as the toll on a person's liver and kidneys some of the life-saving medications people with HIV take—the number of them who could benefit from organ transplants will continue to grow. It is unconscionable to prohibit, or even delay, the important research necessary to make such transplants possible. We look forward to the lifting of the current regulatory ban on such transplants and to the research necessary to potentially make wide-spread positive-to-positive organ transplantations a reality in the near future.

We thank you in advance for your careful consideration of the above comments and sincerely hope that they are of use as you review and revise the Proposed Guidelines. If you have any questions about these comments, or if Lambda Legal and the undersigned can be of further assistance in the

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[8] *See Lawrence v. Texas*, 539 U.S. 558 (2003).

[9] Multiple HIV/AIDS service organizations and medical associations support the lifting of the ban, including the American Medical Association, which recently issued a policy statement in support of amending the law to allow such research to proceed. *See AMA Supports Allowing Research on Organ Transplantation Between HIV-Infected Individuals*, available at http://www.ama-assn.org/ama/pub/news/news/2011-11-14-ama-supports-research-organ-transplantation.page (last visited Dec. 14, 2011).

[10] Furthermore, lifting this ban would also allow the medical community to explore whether organ transplants from HIV-positive donors to fully informed and consenting HIV-negative recipients may be warranted in certain situations.

review and revision process, we would be happy to make ourselves available for further discussion. You may reach us by telephone at (312) 663-4413 x322, or via email at sschoettes@lambdalegal.org.

Sincerely,

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Lambda Legal

AIDS United
amfAR, The Foundation for AIDS Research
The Gay & Lesbian Medical Association

Lambda Legal

Formed in 1973, 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 advocate on behalf of the LGBT communities and people living with HIV throughout the United States.

AIDS United

The mission of AIDS United is to end the AIDS epidemic in the United States. It will achieve this goal through national, regional and local policy/advocacy, strategic grant making, and organizational capacity building. With partners throughout the country, AIDS United works to ensure that people living with and affected by HIV/AIDS have access to the prevention and care services they need and deserve. The organization enables communities to have a direct impact on the epidemic; to mainstream the issue of AIDS at the community level; to encourage the involvement of national philanthropies as well as local philanthropic leaders; to shape public policy and advocacy at the national, state and local levels; and to address critical unmet needs that have marked the epidemic since the start.

amfAR, The Foundation for AIDS Research

amfAR, The Foundation for AIDS Research, is one of the world's leading nonprofit organizations dedicated to the support of AIDS research, HIV prevention, treatment education, and the advocacy of sound AIDS-related public policy. Since 1985, amfAR has invested nearly $325 million in its programs and has awarded grants to more than 2,000 research teams worldwide.

The Gay & Lesbian Medical Association

The Gay & Lesbian Medical Association (GLMA) is the world's largest and oldest association of lesbian, gay, bisexual and transgender (LGBT) healthcare professionals. GLMA's mission is to work to ensure equality in healthcare for LGBT individuals and healthcare professionals, using the medical and health expertise of GLMA members in public policy and advocacy, professional education, patient education and referrals, and the promotion of research. GLMA was founded in 1981 in part as a response to the call to advocate for policy and services to address the growing health crisis that would become the AIDS epidemic.