

## Revising Blood Donation Guidelines for Gay and Bisexual Men

## **Updated January 2011**

In February 2010, Gay Men's Health Crisis released a comprehensive report titled *A Drive for Change*: Reforming *U.S. Blood Donation Policies*. The report addressed the Food and Drug Administration's (FDA) current blood donation guidelines which permanently defer any man who has ever had sex with another man, even once, since 1977, from donating blood. This policy fails to maximize blood safety or to reduce unnecessary discrimination and stigma against gay and bisexual men. The policy does not consider the potential donor's HIV status, frequency or risk of sexual activity, or participation in a monogamous relationship.

There is widespread support by reputable leaders within the public health and blood bank communities who have called for the long-standing policy's review and modification. These leaders include:

- American Association of Blood Banks (AABB)
- American Red Cross
- America's Blood Centers
- In March 2010, Senator John Kerry spearheaded a letter signed by 17 other U.S. Senators calling on the FDA to revisit the policy
- The Health and Human Services Advisory Committee on Blood Safety and Availability (ACSBA) announces it will convene June 10 and 11, 2010 to review the FDA ban on MSM blood donors June
- 33 members of the U.S. House of Representatives and 9 Senators issued a joint letter to the HHS ACSBA calling for a revision to the policy
- Between April June 2010, four local legislative bodies passed resolution calling for a reform to current policy: New York City, the District of Columbia, San Francisco, and Chicago

## Bridging the Gaps Between Donors and Blood Product Users

Both gay men and people with hemophilia have been disproportionately impacted by the HIV epidemic. Critical advancements in HIV prevention, treatment, and research can be linked directly to the years of successful advocacy by both communities. For most of the past quarter century, these two communities have worked toward shared goals, including caring for people living with HIV and preventing the virus's spread. In recent discourse, media often attempted to present the different perspectives as antagonistic. In June

2010, GMHC and several prominent LGBT, HIV, and hemophilia groups issued a joint statement articulating their commitment to the safety of the nation's blood supply and a willingness to carefully revisit the current policy. Among the co-signers of the joint statement were the Committee of Ten Thousand (COTT), Hemophilia Federation of America, National Hemophilia Foundation, and World Federation of Hemophilia.<sup>ii</sup>

In response to the momentum building from blood donor reform advocates, the federal government organized a convening of the Department of Health and Human Services' Advisory Committee on Blood Safety and Availability (ACBSA) to specifically review current blood donation guidelines as they impact gay and bisexual men. On Friday, June 11, after two days of presentations including GMHC's, the ACBSA voted 9 to 6 against recommending a change to the FDA's current policy, citing that currently available scientific data are inadequate to support change to a specific alternative policy.<sup>iii</sup>

However, the ACBSA did find the current deferral policies suboptimal, and unanimously recommended research in the following areas:

- Validate modifications to the donor questionnaire that would better differentiate low versus high risk MSM and heterosexuals, including studies to investigate Transfusion Transmitted Infectious Disease (TTID) and Sexual Transmitted Disease (STD) markers in potential donor subsets;
- 2. Establish ongoing national hemovigilance program for TTID markers in blood donors linked to analysis of demographic, behavioral, and other risk factors:
  - a. Obtain a baseline on prevalence and incidence of TTIDs,
  - b. Characterize risk in different donor subgroups (e.g., younger age), and
  - c. Use above characteristics for continuous quality improvement of the donor deferral process;
- 3. Determine the feasibility of donor pre-testing to limit risk while characterizing donors who might be recruited under modified eligibility criteria;
- 4. Investigate the impact of revised donor criteria on the global availability of plasma products;
- 5. Evaluation of data from other countries that have changed their high risk donor evaluation programs, including MSM; and
- 6. Periodic reassessment of transfusion safety including consideration of multiple and cumulative blood product exposures to recipients.

## **Next Steps**

In response to the ACBSA's decision, the federal government has assembled a working group to devise a comprehensive plan for carrying out the recommendations of the committee. Among the key participants are representatives from the National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI), the FDA, HHS, and the Centers for Disease Control and Prevention. This working group is

expected to release a document with timelines and responsibilities for implementation of the ACBSA recommendations in the coming weeks. GMHC is reaching out to allied LGBT organizations for recruitment of a large number of gay and bisexual men to volunteer for a study that will potentially identify a subset of MSM who are at low-risk for HIV to become blood donors.

Additionally, GMHC is currently promoting the documentary film, *Bad Blood: A Cautionary Tale*, produced by Emmy award winner Marilyn Ness. The film chronicles how the negligence of blood safety regulators and pharmaceutical companies led to 10,000 Americans being infected with HIV through blood transfusion. Utilizing the film as an educational tool for informing mainstream audiences to blood safety, Nathan Schaefer, Director of Public Policy at GMHC, is on a multi-city tour of the film speaking on the history and importance of blood safety and current advocacy efforts for blood donation reform.

For more information, please contact:

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<sup>&</sup>lt;sup>1</sup> A Drive for Change: Reforming U.S. Blood Donation Guidelines

ii Joint Statement on Addressing the MSM Blood Ban

http://www.hhs.gov/ash/bloodsafety/advisorycommittee/index.html

www.badblooddocumentary.com