



Media Advisory

Press Release

June 9, 2010

Statement of the
American Plasma Users Coalition (A-PLUS)
Regarding the MSM Blood Donor Deferral Policy
Before The
Advisory Committee on Blood Safety and Availability
Department of Health and Human Services
June 10-11, 2010
The Universities at Shady Grove, Rockville, MD

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American Plasma Users Coalition, A-PLUS, Seeks FDA-Community Research Agenda to Enhance The Safety of Our Nation's Blood Supply

The Department of Health and Human Services, Advisory Committee On Blood Safety and Availability will be reviewing the current Food and Drug Administration (FDA) policy

recommending that men who have sex with another man (MSM) even one time since 1977 should be deferred indefinitely from donating blood.

Mark Skinner, speaking on behalf of the American Plasma Users Coalition, will deliver the attached statement before the Department of Health and Human Services, Advisory Committee on Blood Safety and Availability (ACBSA), being held June 10-11, 2010 at The Universities at Shady Grove, Rockville, MD.

The A-PLUS, American Plasma Users Coalition, is a national coalition consisting of organizations whose members depend on the blood supply to maintain their health and wellness is speaking with one voice regarding current Donor Deferral Policies, specifically the policy deferring men who have had sex with a man, MSM.

“We acknowledge that the scientific basis for the permanent deferral requires review. We believe that there are a number of factors which should be fully evaluated before making a revision to the policy. Such evaluation and research could lead to a policy revision that maintains or enhances the safety of blood and blood products.”

The Executive Summary of the A-PLUS testimony appears below.

EXECUTIVE SUMMARY

MSM Blood Donor Deferral Policy

The American Plasma Users Coalition (A-PLUS) is a coalition, formerly known as the Plasma User Coalition (PUC), of national patient organizations created to address the unique needs of patients with rare diseases that use life-saving plasma protein therapies. The organizations representing these patients share a common desire to ensure that the patient voice is heard when relevant public policies, regulations, directives, guidelines and recommendations which have a major impact on their access to safe and effective therapy and treatment are considered.

Together our coalition represents more than 125,000 Americans living with chronic disorders dependent upon plasma protein therapies for their daily living. In addition, there are thousands more that remain undiagnosed.

Partners in our coalition include:

Alpha-1 Association
Alpha-1 Foundation
GBS/CIDP Foundation International
Committee of Ten Thousand
Hemophilia Federation of America
Immune Deficiency Foundation
Jeffrey Modell Foundation
National Hemophilia Foundation
Platelet Disorder Support Association
Patient Services Incorporated

A-PLUS appreciates this opportunity to present our views regarding the Advisory Committee on Blood Safety and Availability's (ACBSA) review of the current Food and Drug Administration (FDA) policy recommending that men who have sex with another man (MSM) even one time since 1977 should be deferred indefinitely from donating blood.

Both gay men and those in the plasma user community have been disproportionately impacted by the HIV epidemic. Our communities have a long history of working together on shared goals related to providing HIV support, research advocacy, treatment access, and prevention programs. We share a historical common bond. Together, we are committed to ensuring the overall safety of the nation's blood supply.

At this time, A-PLUS does not believe that the currently available knowledge and data are sufficient to support a change to the existing donor deferral policy. We acknowledge that the scientific basis for the permanent deferral requires review. However, we do not currently have enough information to determine if a one-year, five-year, ten-year, or another deferral period is more appropriate than the existing permanent lifetime deferral. Selection of another interval could also be perceived as arbitrary or lacking scientific foundation. However, this is not the end of the discussion.

We believe that there are a number of factors which should be fully evaluated before making a revision to the policy and we support research focused on high risk behaviors of both MSM and heterosexuals. Such evaluation and research could lead to a policy revision that maintains or enhances the safety of blood and blood products.

Today we are calling for a research agenda to be undertaken to address several critical areas with the following goals:

1. Achieving a better understanding of known and emerging pathogens in specific populations including MSM and heterosexual populations;
2. Developing policy that recognizes societal aspects of the blood system's safety and risk tolerance;
3. Developing alternate donor deferral strategies and the risk of blood-borne diseases;
4. Establishing a framework for accelerated approval of pathogen reduction, removal and/or inactivation technologies for fresh components; and
5. Understanding the implications of a revision on the supply and availability of treatment products globally.

If we progress in earnest with such a research strategy, and obtain reassuring answers, we foresee a time when a revision would be appropriate and donor deferrals could be made on a more individualized, behavioral-based risk review for both MSM and heterosexual donors.

We urge all stakeholders, including donors and end-users, to aggressively work together to seek answers. Equally important, is for the government to commit the necessary funding to ensure that this occurs in a timely manner.

Our specific recommendations for research in the context of the research agenda mentioned above are summarized below.

SUMMARY OF RESEARCH RECOMMENDATIONS

- I. The ACBSA consideration of this issue should not supplant the rigorous scientific review of the FDA and BPAC.**
- II. We must achieve a better understanding of known and emerging pathogens in specific populations including MSM and heterosexual populations.**
- III. We must give due consideration in policy development to the societal aspects of the blood system's safety and risk tolerance.**
- IV. We must consider alternate donor deferral strategies and the resulting risk of blood-borne diseases.**
- V. We must factor into the equation the risk of multiple and cumulative exposure for those dependent upon blood and plasma therapies for their daily living.**
- VI. We must establish a framework for accelerated approval of pathogen reduction, removal and/or inactivation technologies for fresh components and where necessary, support research to develop the technology.**
- VII. We must understand the implications of a revision of the donor deferral policy on the supply and availability of treatment products globally prior to changing the deferral policy.**
- VIII. We must have a robust comprehensive hemovigilance and biovigilance program.**
- IX. We call upon the Department of Health and Human Services to encourage accelerated development and use of pathogen reduction technologies for fresh (labile) components.**
- X. We must implement a robust donor education program as part of any revised donor deferral policy.**