



**AMERICAN  
ASSOCIATION  
OF BLOOD BANKS**

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**Statement of the American Association of Blood Banks  
before the  
Transmissible Spongiform Encephalopathies Advisory Committee**

**January 18, 2001**

The American Association of Blood Banks (AABB) is the professional association for approximately 8,000 individuals and 2,000 institutions, including blood collection centers, hospital-based blood banks and transfusion services. AABB members are involved in all aspects of collection, processing and transfusion of blood, as well as hematopoietic progenitor cells (HPCs). Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in the United States. For more than 50 years, the AABB's highest priority has been to maintain and enhance the safety of the nation's blood supply.

The AABB appreciates the opportunity to comment on the potential deferral of certain donors of human cells and tissues due to the theoretical risk of transmitting Creutzfeldt-Jakob disease (CJD) and vCJD. As we have stated previously before this Committee, the AABB believes that patient welfare must be the utmost consideration when determining whether to implement any new donor deferral policies.

In deciding whether to adopt a policy to defer HPC or transplantable cell or tissue donors who have traveled to the United Kingdom or other countries, the Food and Drug Administration should carefully balance all relevant risks and benefits to patients. It should be noted that the treatment of patients through HPC transplants involves unique patient safety and product supply issues that are different from those involved in the context of blood collections.

HPCs are used in the treatment of patients battling life-threatening conditions, including several cancers and immune disorders. For many patients, HPC transplants represent their last hopes for survival. Successful treatment with HPCs depends on donor selection and appropriate HLA matching. Therefore, HPC donors are often donating their cells for particular individuals, who are frequently relatives. Choice of an HLA match can significantly affect the patient's chance of survival and avoidance of long-term, debilitating chronic graft versus host disease following transplant.

The importance of providing a well-matched HPC unit must be weighed against any potential risks associated with donor exposure to vCJD. Presently, this balancing of risks and benefits is left to the treating physician, in consultation with the patient. Information about UK and other potential deferrals is kept in the donor profile records to be considered by the transplant physician and his or her patient. Other deferral criteria

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currently applied to blood donors do not necessarily automatically apply in the context of HPCs. For example, in certain instances patients are given bone marrow that tests positive for certain bacteria or pathogen markers. Transplant of such units is considered medically acceptable given extreme circumstances and the severity of the patient's underlying condition.

Given the unique circumstances involving HPC transplants, the AABB strongly believes that further inquiry into the possible effects of a CJD-related deferral policy should be undertaken before adopting a new policy for HPCs. This inquiry should involve the advice and counsel of treating physicians, patient advocates, and medical ethicists and should consider the unique range of issues facing severely ill patients awaiting HPC transplants.

The AABB would welcome the opportunity to work with the Committee, the FDA, and others in the transplant community in addressing this important issue. Together, we must all strive to ensure that patients depending on HPC transplants receive the best possible care.