



## **Statement to the Food and Drug Administration's Transmissible Spongiform Encephalopathies Committee**

**01 June 2015**

### **Reconsideration of the FDA's geographically-based donor deferral policies to reduce the risk of transfusion-transmitted variant Creutzfeldt-Jakob disease**

**Presented by  
M. Allene Carr-Greer, Director, Regulatory Affairs**

Thank you for the opportunity to present this statement. We appreciate the commitment the FDA has made to periodically revisit its policy on geographically-based donor deferral policies related to vCJD and we are in agreement with Option 2 presented for consideration to the Committee today. As presented in the Issue Summary and summarized in Table 3, Option 2 (evaluating donors for cumulative time, equal to or greater than 5 years, spent in France and Ireland from 1980-2001, rather than Europe from 1980 to present) will provide similar risk reduction for transfusion-transmitted vCJD as the current policy. Determining a time limit on exposure in France and Ireland rather than leaving it open ended to the present is consistent with the period of exposure, as was the case when defining the risk period for the UK. At the same time it should result in fewer donors lost and will be less complex to implement. Currently, lists of particular countries that are the countries of interest in Europe must be available to staff and donors.

We ask the FDA to clarify the process that can be used to reenter donors previously deferred for their potential exposures outside of the UK, France and Ireland. It is our understanding that donors would continue to be deferred for potential risk from transfusion in the UK and France as well as time associated with military bases (commissaries) in Europe. Evaluating donors for potential association with military bases introduces complexity and the opportunity for errors, and we would like to see FDA modelling extended to justify these continued deferrals. In keeping with the FDA's commitment to ongoing evaluation of vCJD deferral policies we ask that the agency seek a collaboration with colleagues in the military and use the data on individuals associated with these military bases from 1980-1996. There have been no cases of vCJD publicly reported in any individuals associated with the US military. Among other deferred donors there are many younger adults born while living on, or associated with these military bases, who are not allowed to donate blood.

For your information below are the 4 questions on the AABB full-length DHQ currently used to evaluate donors for vCJD risk.

1. From 1980 through 1996 did you spend time that adds up to 3 months or more in the United Kingdom?
2. From 1980 through 1996 were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?
  - a. The two timelines for north / south of the Alps (1980-90 and 1980-96) are managed on the follow-up flowchart
3. From 1980 to the present did you spend time that adds up to 5 years or more in Europe?
4. From 1980 to the present did you receive a blood transfusion in the United Kingdom or France?

Question 2, as mentioned previously, is complex, error-prone when administering, and results in what we believe are unnecessary donor deferrals. The option before the committee today regarding cumulative time in France and Ireland will update Question 3.

We include receipt of beef insulin from the UK on our Medication Deferral List and would appreciate understanding what evidence supports its continued application. Removal of bovine insulin from the MDL will potentially focus our donors on more important considerations.

Again, we thank the FDA for bringing these data to the Committee today and for the opportunity to publicly support a move toward Option 2.

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 2,000 institutions and 8,000 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Since 1962, the Armed Services Blood Program has served as the sole provider of blood for the United States military. As a tri-service organization, the ASBP collects, processes, stores and distributes blood and blood products to Soldiers, Sailors, Airmen, Marines and their families worldwide. As one of four national blood collection organizations trusted to ensure the nation has a safe, potent blood supply, the ASBP works closely with our civilian counterparts by sharing donors on military installations where there are no military blood collection centers and by sharing blood products in times of need to maximize availability of this national treasure.