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**Impact of vCJD Travel Deferrals on the Blood Supply
Statement before the Transmissible Spongiform Encephalopathies
Advisory Committee, Food and Drug Administration
February 20, 2003**

Presented by Celso Bianco, MD, Executive Vice President

America's Blood Centers (ABC) is a national network of locally controlled, non-profit community blood centers that provide nearly half of the U.S. blood supply from volunteer donors. Collectively, we operate in 45 states and serve more than half of the nation's 6,000 hospitals. America's Blood Centers' total blood collections exceeded 7 million donations in 2001. We thank FDA for asking us to comment on the impact of the implementation of extended donor deferrals for vCJD on October 31, 2002.

Impact of the vCJD related travel deferrals

All 74 ABC members in the US implemented the new vCJD deferrals by October 1, 2002. Surveys of ABC member centers show that from 2001 to 2002 the average percentage of donors who came in and were deferred for travel related to vCJD increased from 0.2% to 0.7% of donor registered--or over 56,000 donors. The deferral rate for individual centers in 2002 ranged from 0.5% to 1.1%. These deferred donors had donated an average of 1.9 times a year for an estimated total loss of over 107,000 donations this year.

More worrisome is the fact that 75% of the deferred individuals were repeat donors. These are our most dedicated and safest blood donors, because they have donated many times and have been tested and found negative for known transfusion transmitted diseases in each donation they made, until they were deferred for a vCJD travel risk. The donation frequency of deferred donors is shown in Figure 1. This donor loss is even more pronounced among those who donate platelets by apheresis. ABC's survey showed that the deferred plateletpheresis donors had donated an average of 4.2 times a year. We lost almost 2,800 apheresis platelet donors in 2002. With the deferrals fully implemented in 2003, we expect to lose over 13,700 apheresis donations.

As expected, vCJD related deferrals now have become a substantial component among all deferrals. In 2001, they constituted only 1.2% of all deferrals as compared to 5.5% in 2002 (with a range 0.4 to 11.4%). Figure 2 highlights the increase, particularly for apheresis donors. A previous ABC survey, conducted in October 2002, showed that deferral of military personnel constituted a major proportion of the vCJD related deferrals, because military personnel and their families have been dedicated contributors to the civilian blood supply. Some ABC centers are also seeing substantial deferrals of high school and college students because they were military dependents and were born or lived in Europe for extended periods of time. Other blood centers have told us that they have seen significant attrition of donors at corporate blood drives with multi-national companies whose employees and families routinely are posted in Europe for extended periods of time.

It should be emphasized that all these recorded deferrals occurred at the donation site, in the course of pre-donation medical history. These donors showed up to donate and were sent back home. Unfortunately, we are unable to measure the number of potential donors who learned about the vCJD deferrals through the information provided by blood centers or the media, and did not show up to donate. Nor do they capture donors deferred during prescreening by blood center telemarketers. We strongly

suspect that these deferrals exceed the number of donors deferred at the donation sites by several fold. A survey performed by an ABC member center in California showed that 5.3% of active donors were affected by implementation of the vCJD guidance.

Impact on the blood supply of ABC member centers. We are just coming out of the worst January blood shortage that we have seen in many years. The volunteer blood sector, already stretched by the impact of vCJD deferrals, was confronted with two weeks of holidays. Christmas and New Year's Day fell on Wednesdays, making blood drives at offices, churches and schools almost impossible. This is clearly shown in Figure 3, taken from the ABC website www.americasblood.org. ABC members post their inventory status (green - 3 days or more, yellow - 2 days, and red - one day or less) via an Internet program that creates automatically a daily summary report. These postings are available to the public. Just click on the spotlight!

It is time to reconsider the vCJD travel related deferrals. We all share a common purpose: the availability of a safe and adequate blood supply that meets patient's needs. Concerns about the possible transmission of vCJD by transfusion of blood and blood products have led us to implement strict donor deferral policies, based on the precautionary principle. However,

- While we recognize that evidence about the *potential* for transmission of TSEs in animal models continues to develop, we still lack evidence of actual *transmission* among transfusion recipients in the UK or elsewhere, including patients that receive multiple transfusions, and recipients of clotting factor concentrates.
- The incubation period for iatrogenic cases of CJD is in general less than 13 years. The predicted incubation period of vCJD, based on the cluster of 5 cases in Queniborough, UK is 15 years (according to Chris Prowse, Director of the Scottish Blood Transfusion Service). The BSE epidemic in the UK cattle herd peaked in 1988 (by date of birth). Thus, we should have already seen at least some cases of transmission by blood at this time.
- The ongoing UK follow-up study of donors who later developed vCJD and recipients of blood from these donors has not yielded a single case, as shown in Table 1.
- The number of reported cases of vCJD is declining, as shown in Figure 4. After seven years of increasingly intense surveillance, there are 130 cases reported in the UK.

Conclusion. We believe that it is time to reconsider and relax at least some of the geographical vCJD deferrals. While we understand the public desire for zero risk, we believe that the precautionary principle has been inappropriately applied in this case. It is time to analyze the available data and recognize that the theoretical risk has not materialized. Is it possible that the epidemiological information will change? Yes, it is. However, if this is the case, we would reinstate the strict deferrals and whatever other measures are appropriate at that time.

We have a multitude of real blood safety issues to contend with at the present time. There is a worrisome shortage of blood donors and increased demand because of blood-intensive procedures like bone marrow transplants, organ transplants and aggressive chemotherapy. We also urgently need to address other diseases for which transfusion-transmission has been demonstrated—such as West Nile virus. As of February 5, 2003 this disease has caused 4,008 cases of meningoencephalitis and 263 deaths in the US, with close to 600,000 individuals infected with the virus. This epidemic has occurred in a single year, not in the 20 years of BSE or 7 years of vCJD.

Many scientists and biotechnology companies are attempting to develop a test to screen blood donors for vCJD. Unfortunately, there is no test on the horizon because the levels of prion protein in blood of experimental animals are too low for detection with available technologies. Let's accept the fact that all epidemiological studies performed in humans show that the risk of transmission by transfusion, if any, is extremely small. Let's relax the deferrals at least partially and help patients whose lives depend on a steady supply of blood. Thank you for the opportunity to present our point of view.

Table 1. UK Forward and Reverse Lookback (TMER)*

114 vCJD cases	114 vCJD cases
20 said to be blood donors	8 reported to be transfusion recipients
11 Identified	4 identified, 2 not Tx, 2 pre-records
9 donated	
56 components	117 components Tx 103 to one vCJD case
29 recorded Tx	111 donors traced
None on CJD register	None on CJD register

*Data from P. Hewitt presented by Chris Prowse, Director of the Scottish National Blood Transfusion Service at the International Society of Blood Transfusion in Vancouver, August 2002.

Figure 1 Donation frequency of donors deferred because of vCJD related travel.

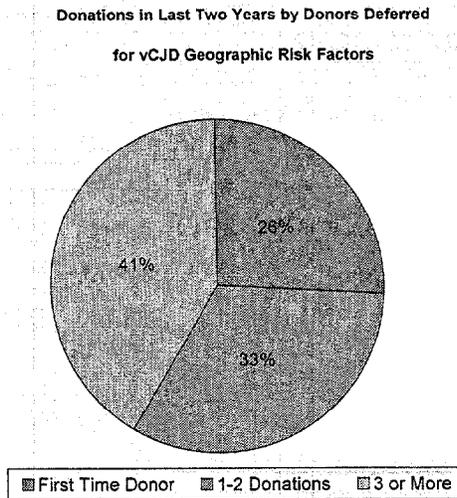


Figure 2. Comparison of donor deferrals in 2001 and 2002.

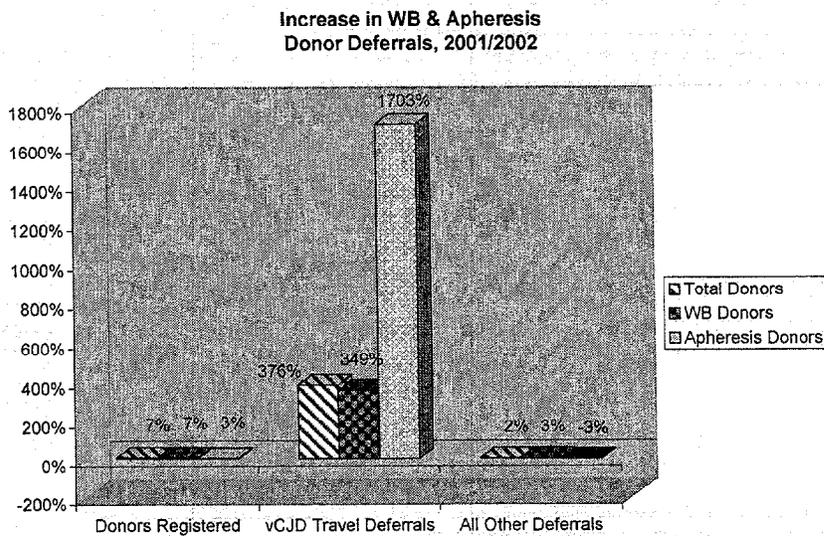


Figure 3. ABC Blood Supply in the past 3 months according to reports posted in the ABC Stoplight.

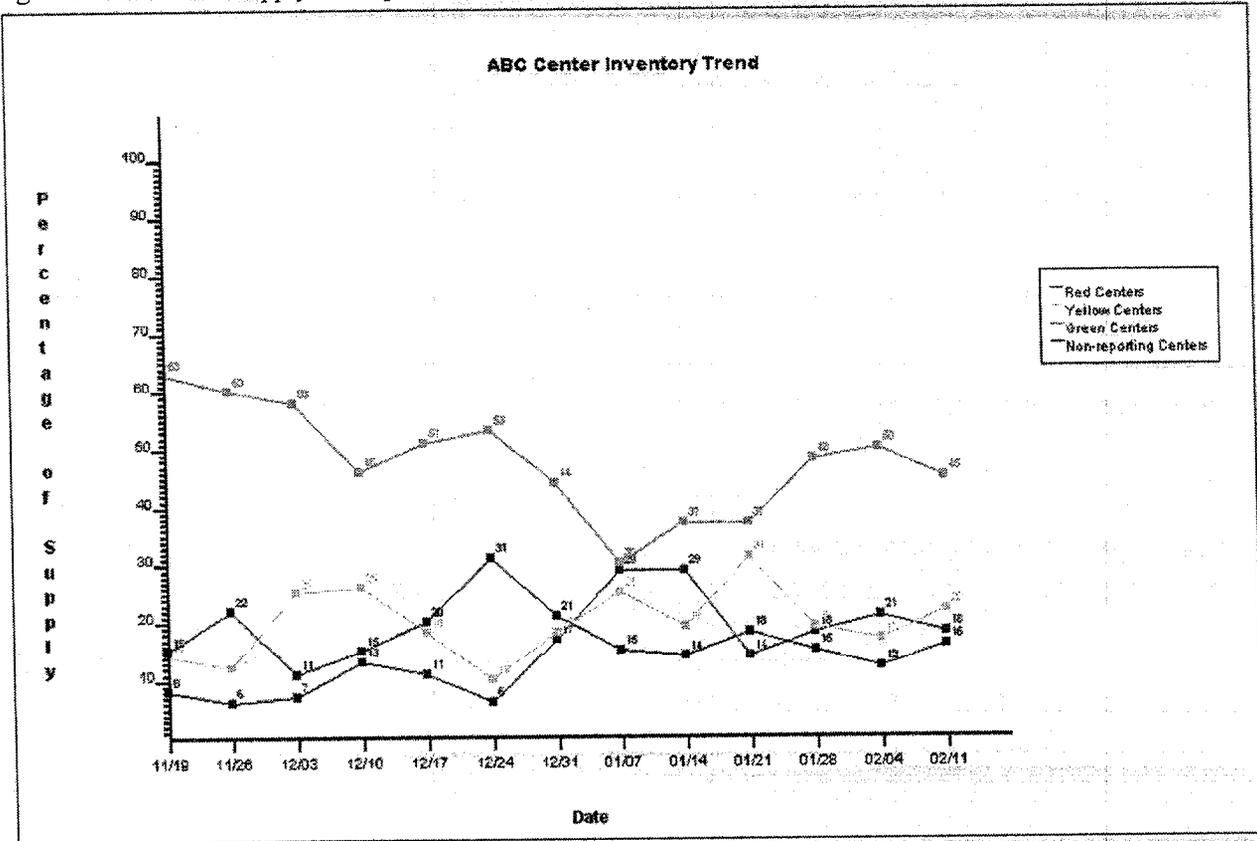
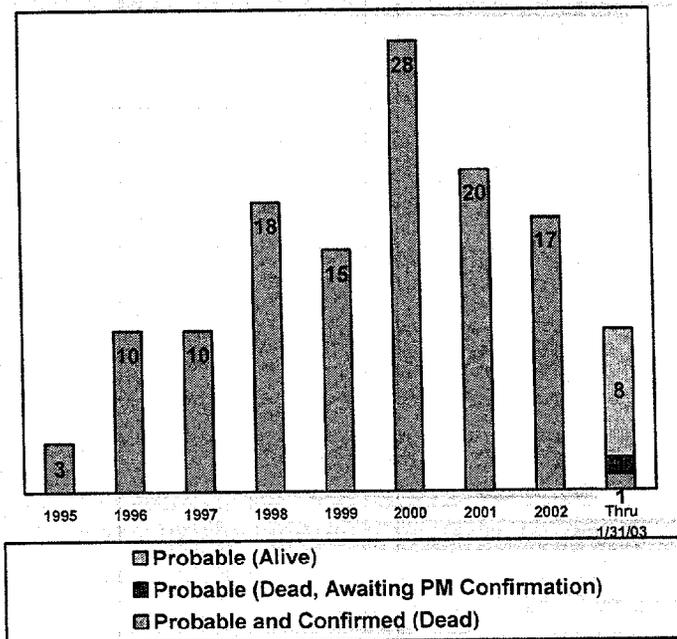


Figure 4. Number of cases of vCJD reported by the UK Department of Health as of February 3, 2003



Total Deaths from definite or probable vCJD: 122
 Deaths from definite vCJD (confirmed): 94
 Deaths from probable vCJD (without neuropathological confirmation): 27
 Deaths from probable vCJD (neuropathological confirmation pending): 1
 Number of probable vCJD cases still alive: 8