Draft Summary of the
Joint Meeting
of the
Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC)
and the
Blood Products Advisory Committee (BPAC)
January 17, 2002

The committee was given an overview of the January 2002, Guidance for Industry on the "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant CJD (vCJD) by Blood and Blood Products". The committee and the public commented on this Guidance and its potential effect on blood safety and availability. The Committee Chair stated that industry and the government needed to work together to increase donor education and blood donor recruitment. While there were some proposed changes to the guidance document, the consensus was that we should wait to see the effect of this Guidance before we start to modify it.

The committee was then updated by researchers from industry (Christopher Healey, JD, PPTA; Douglas Lee, PhD, Bayer Corporation; Martin Vey, PhD, Aventis Behring and Thomas Kreil, PhD, Baxter Bioscience) on the clearance of spiked TSE infectivity and the protease-resistant prion proteins by plasma processing. The committee stated that this research was needed and encouraging in that it demonstrated that the plasma product manufacturing processes substantially reduced the infectivity spiked into plasma under these experimental conditions. While these studies along with the donor deferral appear to reduce markedly the risk of plasma product infectivity, there is still the theoretical risk of transmission of infectivity at these reduced levels.

Committee Discussion Topic 1: Effectiveness of measures taken to protect humans from food-borne exposure to the agent of bovine spongiform encephalopathy (BSE): Implications for risk of variant Creutzfeldt-Jakob disease (vCJD) and blood safety.

Issue: FDA requested advice on whether food chain controls for preventing human exposure to BSE as implemented in the UK since 1996 provide a sufficient basis to obviate the need to defer blood and plasma donors based on subsequent travel or residence in a BSE risk country.

Charge: The committees were asked to evaluate the probable effectiveness of those measures taken by the UK to protect humans from food-borne exposure to the BSE agent and their value in mitigating risk otherwise addressed through donor deferral.

Questions presented to the Committees:

1. Do members of the committee agree that the combination of measures implemented in the UK by the end of 1996 to protect the human food chain from BSE contamination are sufficient to obviate the need for donor deferrals based on subsequent travel or residence in the UK?

The committee voted: 25 yes votes, 0 no votes, and 0 abstentions. The non-voting industry representative concurred with the "yes" votes.

2. If the answer to Question 1 is "yes," which measures should the FDA consider to be of greatest importance when it considers future revisions in recommendations for determining the suitability of donors who spent time in other BSE countries?

Committee members stated the following measures were important:

- **Age-based slaughter schemes (30 month slaughter rule)**
- **Prohibition of sale for human consumption of meat products recovered by methods likely to contaminate the products with high-risk materials ("advanced or mechanical meat recovery systems", ARM or MRM)**
- **Removal of "specific risk materials"(SRM including tissues such as: CNS, lymphoid and intestinal tissues).**
- **Monitoring and surveillance programs**
- **Immediate condemnation and prompt destruction of animals showing signs of BSE with adequate compensation to owners.**

3. If the answer to Question 1 is "no," what other measures, if any, would committee members consider sufficient to obviate the need for donor deferrals based on subsequent travel or residence in a BSE-endemic country?

Although the answer to question 1 was "yes" the committee stated that, along with the answer to question number two (above), they wanted to emphasize the importance of surveillance and monitoring in order to make sure that the measures stated above were fully implemented and consistently enforced.

In the afternoon Dr. George M. Gray updated the committee on the "Harvard BSE Risk Assessment". He reported that due to the current safeguards in place in the US today, and based on the assumptions used in their model, that if BSE/TSE infectivity spread to the US dairy/beef cattle population that there would not be any self-propagating spread of infectivity and the risk of human exposure to infectious cattle tissue would be low.

This summary was written to give a brief overview of the meeting until the official transcripts are available. Please see the official transcripts for a detailed account of the committee discussions.