"Quick Summary"
For the June 1 & 2, 2000
Transmissible Spongiform encephalopathy Advisory Committee Meeting

JUNE 1, 2000, DONOR DEFERRAL

CHARGE

The FDA asked the TSEAC to evaluate new information that has become available concerning new variant CJD and BSE in France and BSE in European countries besides France and the UK. The committee was asked to consider the risk that donors traveling or resident in France and other BSE countries outside the UK might have been exposed to and infected by the BSE agent and that their blood, blood components and plasma derivatives might transmit infection to recipients.

The Committee was also asked to consider, in the context of a risk-benefit estimate, any effects that recent changes in blood-donor deferral policy may have had on the blood supply in the United States as well as effects reasonably to be anticipated if additional deferrals of donors are recommended.

QUESTIONS

1. Do the Committee members believe that available scientific data on the risk of vCJD warrant a change in the current FDA policy regarding deferrals of blood and plasma donors based on a history of travel or residence in the UK? Please comment.

The committee voted: 3 Yes votes, 15 No votes, and 0 abstentions.

The committee stated that there was not strong data to support changing the UK position from what was recommended last year. Also there was not sufficient time to understand the impact of the current policy on availability. Therefore, the committee voted not to change FDA's newly implemented policy on deferral of UK donors.

2. Considering the current scientific data on the risk of vCJD and the potential impact on the blood supply, should FDA recommend deferral from blood or plasma donation for persons with a history of travel or residence in France?

The Committee voted: 1 Yes vote, 17 No votes, and 0 abstentions.

The data presented clearly revealed less risk of nvCJD in France as compared to the UK. While the committee encouraged all countries to work to eliminate BSE and thus to reduce vCJD and the theoretical risk of transfusion transmitted vCJD, they voted against deferral of blood or plasma from persons with a history of travel or residence in France .

3. Should FDA recommend deferral from blood or plasma donation for persons with a history of travel or residence in BSE countries other than the UK and France (without reported vCJD)?

The committee voted: 1 yes vote, 17 no votes, and 0 abstained.

This vote reflected the conclusion of a lower risk in these other countries . The committee emphasized that FDA deferral policy needs a periodic reassessment as more information is obtained.

TSEAC Quick summary (page 2)

JUNE 1, 2000, – Leukoreduction

CHARGE:

TSEAC was asked to consider whether leukoreduction of blood and blood components might be expected to reduce substantially the theoretical risk of transmitting the CJD or nvCJD agent, and if they would recommend universal leukoreduction of blood and blood components as a risk reduction measure for CJD and nvCJD.

QUESTION:

Can leukoreduction significantly reduce the infectivity of CJD and vCJD? For what blood components?

The Committee commented that available date were insufficient to make a scientific decision. With that clarification, the vote was: 2 yes votes, 12 no votes, and 1 abstention.