AMERICAN
ASSOCIATION
OF BLOOD BANKS

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No.97D-0318

Draft Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products

Dear Docket Officer:

The AABB interorganizational Task Force for redesigning the Uniform Donor History Questionnaire (UDHQ) submits these additional comments to the docket. As stated in our initial comment letter of October 10, 2001, in order to obtain additional insight into the questions, the task force intended to subject the proposed FDA questions and the task force recommended changes to focus groups The task force has now completed that project and wishes to amend and clarify our initial comments to Docket No. 97D-0318.

The methodology used for conducting the focus groups is described in the peer-reviewed journal *Transfusion*, November 2000. Four focus groups were utilized: one high school group, one minority group, one business group, and one group representing the military. The following task force recommendations are based on input from these focus groups, and are not identical to all of the previous recommendations. The original recommendations were made based on the task force concept of a simplified questionnaire utilizing time periods as headers and simplifying all of the specific questions related to that time period asked under that header. Recommendations were made with this concept in mind, and when translated into language for the current type of questions, did not always prove to be appropriate.

Section IV B Recommended Questions to Identify Donors Increased Risk for CJD

Question 1)

The task force still proposes the following wording:

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"Have any of your relatives had Creutzfeldt-Jakob Disease (CJD)?"

Rationale: Focus groups were not specifically queried on this issue since FDA representatives to the task force have already indicated that FDA agrees with this approach

Question 2)

The task force still proposes the following wording:

"Have you ever received growth hormone from human pituitary glands?

Rationale: All focus groups preferred the task force recommended language. The task force feels this language is less likely to result in false positive answers. A variety of products known as human growth hormone are available from health food stores. It is important to indicate that these are not cause for deferral. By adding the words "from human pituitary glands" it is likely that this wording will help individuals to distinguish the health food store product from the products possibly contaminated with prions (i.e., human pituitary derived). In addition, the task force considered the possibility of simply asking about human growth hormone, but determined that the question was too broad, and might defer donors who are taking recombinant growth hormone.

In the final simplified donor history questionnaire, the task force intends to place this medication on the medication deferral list. Utilizing this approach, we will not ask specific questions about each medication. Instead, there will be one general capture question about medication. The donor will then be given a list of medications indicating deferral time periods and asked to review it. (See attached draft. This draft is currently being evaluated by the National Center for Health Statistics' cognitive interviewing project). The donor will then be asked whether he/she has taken or is taking any of these medications.

Question 3)

The task force supports the FDA proposed wording "Have you received a dura mater (or brain covering draft)?

Rationale: New focus groups were not specifically queried on this question since it has been in use for a number of years and has been included in other task force studies. There is no indication that donors have difficulty understanding this question.

Section IV D Recommended Questions for Identifying Donors at Risk for Exposure to BSE

1. **To identify donors with Geographic Risk of BSE Exposure: Phase One**

Question 1)

The task force had originally proposed, "Between 1980 and 1996 did you spend time that adds up to three months or more in the United Kingdom?"

We now withdraw that suggestion and recommend:

"**From 1980 through 1996** did you spend time that adds up to three months or more in the following countries? (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands)"

Rationale: The focus groups pointed out that "between 1980 and 1996" could be interpreted as not including either 1980 or 1996. They noted that "from 1980 through 1996" is less ambiguous. (Please note that the proposed FDA language for questions 2, 3, 4, and 5, also use the "between *year* and *year*" and has this same difficulty.) As currently envisioned, the final simplified donor questionnaire will have major headers for the various time periods. One of these headers will be 1980 through 1996.

In addition, the task force now wishes to alert the FDA to concerns about the geographic definition of the UK. Legally, the Channel Islands are self-governing and are not part of the UK. In addition, Gibraltar and the Falkland Islands are colonies of the UK but are only two among many others. Finally, the islands of Jersey, Guernsey and Isle of Man are all "dependencies of the crown". In order to avoid confusion about what constitutes the UK, the task force suggests eliminating the use of the term United Kingdom, and instead providing the potential donor with a list of countries considered to have the same risk factors.

Question 5)

The task force again recommends that Question 5 become Question 2 and delete the listing of the countries defined as the UK. This question would read:

"**Since 1980**, have you received a transfusion of blood, platelets, or plasma in any of these countries?"

Rationale: The focus groups indicated that any individual who answered no to the travel question might skip over the transfusion question without realizing the difference in time periods. All focus groups recommended bolding the time frame to emphasize the difference in time frame. Again, the intent of the task force is to list questions under a specific time period in the simplified questionnaire.

Question 4)

The task force continues to propose, "Since 1980, have you spent time that adds up to five years or more in France?"

Rationale: All focus groups preferred this language and had no other recommendations. Again, in anticipation of future changes in which more countries would be included, the task force suggests that FDA consider use of a list of countries rather than including the name of the country in the actual question.

Question 2 and 3)

The task force had originally recommended: Are you a current or former member of the U.S. military, a civilian military employee, or a dependent?

If answer is "yes," ask: Between 1980 and 1996 have you been stationed for 6 months or more in a BSE risk country?

The task force withdraws its previous recommendation and now suggests the following language:

"From 1980 through 1996, were you employed by the Department of Defense, or a dependent of someone employed by the Department of Defense?"

If *yes,* Did you spend a total time of 6 months or more in any of these countries? *(List of countries will be provided)*

Rationale: Although the focus groups preferred the proposed task force questions to those of the FDA, they expressed a number of concerns about the task force questions as well and suggested the above revisions. They indicated concern that not putting the time frame in the first task force proposed question would confuse what time period applies to "former member". The military group also noted that the terms "current or former members of the U.S. military, a civilian military employee, or a dependent" and "stationed" might not capture all individuals who are at risk. Independent contractors may not consider themselves civilian military employees. Contractors and military employees on temporary assignment may not consider themselves "stationed" at a particular military base. However they would very likely eat on base, and thus would be potentially subject to BSE exposure.

Focus groups also concluded that "BSE risk countries" was a confusing term, pointing out that the current questionnaires do not have a question that asks specifically about malaria risk countries. Focus groups suggested presenting the donor with a list of BSE risk countries. The task force is recommending that the FDA prepare and update this list.

2. **To identify donors of whole blood who have additional geographic risk of BSE exposure: Phase II**

The original task force proposal was: Since 1980 have you spent time that adds up to 5 years or more in BSE risk countries? (includes time spent in the UK)

The task force withdraws that recommendation and now proposes the following language:

"Since 1980 have you spent time that adds up to five years or more in any of these countries?"

Rationale: Focus groups preferred the task force-proposed question to the FDA-proposed question. Focus groups again pointed out that "BSE risk countries" was a confusing term, and suggested the donor be given a list of countries to review. This list should be prepared and periodically updated by the FDA, and would include the UK and all of the countries considered part of the UK.

3. **To identify donors who have been injected with bovine insulin**

The task force proposal remains:

"Since 1980, have you ever injected bovine (beef) insulin?"

Rationale: Simplification of language. Starting the question with the time frame retains consistency with the approach for other questions. However, in the simplified history questionnaire, this will be included in the medication list rather than as a separate question. (See previous discussion and attached draft medication list.)

Finally, the task force would like to encourage the FDA to consider a potential new approach to travel questions. As more and more geographic information relating to travel is needed, the task force has re-examined this issue. As a result of focus group input, the task force is now considering a section devoted entirely to travel questions. We are including this information in the letter to this docket because such a section would affect the questions relating to vCJD.

The travel section would begin with a capture question that would be followed by more detailed questions if the donor answered yes.

Have you ever lived or traveled outside of the US or Canada?

If no, the donor moves to the next set of questions.

*If yes: (*the questions that would result in an indefinite deferral would be asked first, from most likely to least likely to be affirmative*)*

A. "**From 1980 through 1996** did you spend time that adds up to three months or more in these countries? (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands)"

If no, go to B.

B. "Since 1980 have you spent time that adds up to five years or more in any of these countries?

Note: A list of BSE risk countries would be provided including those in the UK. Currently this list would contain only France.

If no, go to C.

C. "From 1980 through 1996, were you employed by the Department of Defense, or were you a dependent of someone employed by the Department of Defense?"

If no, go to D.

If *yes,* Did you spend a total time of 6 months or more in any of these countries? *(List of countries will be provided)*

If no, go to D.

D. Since 1977 did you spend time in Africa?

If no, go to E.

If yes, Did you spend time in any of the following countries?

If not an African country requiring deferral, go to E.

E. Were you ever transfused with blood, platelets or plasma in the United Kingdom or Africa?

If no, go to E.

If yes, Where?

If not an African country requiring deferral, go to E.

If UK, Was it since 1980?

If no, go to E.

F. Was your travel in the past 3 years?

If no, go to next set of questions.

If yes, Where? *Interviewer will check for malaria risk (i.e.* The CDC Yellow Book *" Health Information for International Travelers").*

If not deferred, go to next set of questions.

The task force is still discussing this proposal, and has not yet finalized the exact sequence of the travel questions. The task force will submit the final version to the FDA for approval. However, we included the concept in these comments to the docket for this draft guidance so that this approach would be considered for the donor questions for CJD and vCJD risk.

The AABB Uniform Donor History Task Force appreciates this opportunity to comment on this important donor screening issue. If you have any questions, please contact Kay Gregory at kayg@aabb or 901-842-2790.

Sincerely,

Joy L. Fridey, MD (atw)

Joy L Fridey MD
Chair, UDHQ Task Force

IF You Have Taken Any of These Prescription Medications You Should NOT Donate Blood at This Time

Why do we ask about medications you are taking or may have taken in the past?

Blood products from donors taking certain medications may contain significant levels of these medications. Transfusion of blood products containing these medications could result in problems in certain ill recipients or could cause problems or birth defects in the developing fetus of a pregnant blood recipient. Such medications include:

- **FDA recommends that donors taking the following medications do not donate until at least one month after the last dose of the medication:**
  - **Proscar (finasteride)** is a medication prescribed for the treatment of benign prostatic hypertrophy (BPH).
  - **Propecia (finasteride)** is a medication prescribed to promote hair growth in men with baldness.
  - **Accutane (isotretinoin)** is a medication prescribed for the treatment of severe, unresponsive acne.
- **FDA recommends that donors taking the following medications do not donate until at least 3 years after the last dose of the medication:**
  - **Soriatane (acitretin)** is a medication prescribed for the treatment of severe, unresponsive psoriasis. This medication can be found in the blood for several months after the last dose.
- **FDA recommends that a donor who is taking or has ever taken the following medications be permanently deferred from donating blood.**
  - **Tegison (etretinate)** is a medication prescribed for the treatment of severe, unresponsive psoriasis. It is not known how long it takes to clear this medication from the body after the last dose.

FDA recommends that a donor who has taken the following medications be permanently deferred from donating blood. Certain medications may be associated with Creutzfeldt-Jakob Disease (CJD). Such medications include:

- **Human Pituitary-derived Growth Hormone** is a medication given prior to 1985 for the long-term treatment of children with delayed growth. This medication was extracted from human pituitaries. Some patients who received this hormone were later found to have a rare neurological disease called Creutzfeldt-Jakob disease (CJD). CJD has **NOT** been associated with the growth hormone preparations available since 1985.
- **Bovine-derived (beef) Insulin** is an injected medication used to treat Diabetes Mellitus. Bovine-derived insulin imported from countries with Bovine Spongiform Encephalopathy ("Mad Cow Disease") could contain material derived from infected cattle. Anyone using Bovine Insulin at any time since 1980 should not donate blood.