Puget Sound Blood Center
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October 31, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane rm. 1061
Rockville, MD 20852

Subject: Comments on Revised Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products--Draft Guidance to Industry

To Whom It May Concern:

Public safety is imperative. While vCJD represents only theoretical risk to the blood supply, it is reasonable to take precautionary measures to reduce potential transmission. Despite being rationalized by a 90% reduction in risk, the draft recommendations are nearly impractical to implement as detailed in this guidance. The varied phases and associated geographical permutations are baffling. The end result being donor confusion and increased costs associated with the production of two versions of donor questionnaires and associated criterion. If public health is substantially protected by these measures, they should be implemented simultaneously, without regard to phasing.

The exclusion criteria, as presented in this draft guidance, are not easily applied. Chances are, most institutions are going to be faced with simplifying the presentation to the donor. Our recommendation supports this approach. One question should be posed to the donor, "Have you spent a total of three months or more in Europe between 1980 and the present?" Based on an affirmative response, further history would be obtained. A denial of European travel between 1980 to present would negate the need to query any further.

More specific comments include:

- This Draft Guidance states that CJD guidance regarding iatrogenic, familial, and sporadic remains unchanged. However, there are changes (e.g., "reentry" of donors with familial CJD). This guidance should simply supercede prior memos and documents on both CJD and vCJD.

- Does the European deferral consider cumulative travel/residence (as defined for France) or only contiguous residency?

- Reentry is a misleading term. The donor may be able to provide the necessary information at the initial presentation. Rather, these explanations should simply exclude familial CJD and not be structured in any sort of "re-entry" argument.

- Section IVD: Recommends that the questions be asked face-to-face, at least when the donor is asked the questions for the first time and to require that computerized interview programs include audio. This requirement should be removed. There is no obvious justification for elevating these deferral questions to a higher status than is required for many other questions on donor conditions and behaviors. It greatly complicates the screening process for those establishments that do not now conduct face-to-face interviews, a practice that has been found acceptable by the FDA.

- IVD, 2: States that the Phase II questioning should be implemented only for Whole Blood donors. The intent was to exempt Source Plasma donation, but it should be made clear that donors of other allogeneic components (e.g. platelets, plasma) should be so screened.

- The term "at risk" and "risk factors" seem to apply to different things in different places in the document. This is confusing. The terms should be carefully defined so they are consistent throughout.

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- Section VI is unclear. The first two sentences are internally inconsistent.

- Recommendations to "appropriately counsel" the donor should be deleted. The usual deferral procedures should be adequate.

- 9 CFR 94.18, the citation for countries with BSE risk, lists Oman as having BSE yet it is not in the draft Guidance nor would it be detected via the European exclusion.

- If indeed Gibraltar and the Falkland Islands are part of the United Kingdom, it is doubtful that most people would know it. These were not part of the predecessor guidance on the UK (11/99). Are these regions being deliberately added?

- "Question 5) Have you received a transfusion of blood, platelets, or plasma in the United Kingdom, between 1980 and the present?" Does cryo count? It is best to reference a transfusion rather than the different blood components unless they are germane to deferral categories.

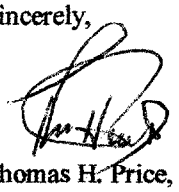
- Plenty of blood establishments produce recovered plasma while bearing licenses for Source Plasma and plasma for transfusion. Therefore, they already have mechanisms in place for differentiating the products. If the guidance is risk-based, establishments should be permitted to exercise due discretion in treating the recovered plasma and Source Plasma equally. There should be no requirement that recovered plasma be discarded while Source Plasma continues to be sent for further manufacture, particularly in cases of post-donation information.

- Given the confidence that the manufacturing processes for plasma derivatives denature CJD prions, then why is plasma sent for further manufacture (recovered plasma and Source Plasma) subject to consignee notification and retrieval? Recovered plasma and Source Plasma should be bound to the same requirements if the risk is equivalent.

- The complexities of donor deferral are daunting enough—not to mention the elaborate machinations required applying the notification and retrieval criteria. Does it really need to be so complex? Withdrawing in-date product is straightforward. All other retrievals are for further manufacture or have been transfused. Further manufacture is considered low risk due to the inactivation processes, so consignee notification and retrieval for destruction should be unnecessary (save for vCJD). Transfused products require no further action (again, save for vCJD). All the details surrounding product retrieval should be simplified to retrieve in-date products for transfusion save for vCJD or suspected vCJD (see attachment).

Again, it is in the public's best interest that the presentation of this information be clear and cogent. Please consider these comments in promoting such an approach. Contact Linda Barnes at (206) 292 4688 should you have any questions about these points.

Sincerely,



Thomas H. Price, MD
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Linda S. Barnes, RAC
Director, Quality Assurance/Regulatory Affairs

Attachment

Type of Risk	Donor Deferral Criteria	Recommendations for product retrieval and quarantine			Recipient Tracing and Notification
		Blood Components	Plasma Derivatives	Consignee Notification	
diagnosed with vCJD	~~permanently defer~~ **indefinitely defer**	immediately retrieve and quarantine for subsequent destruction all in-date blood components under your control	immediately retrieve and quarantine for subsequent destruction all in-date blood components under your control	*within one wk of receiving post-donation information*, notify all consignees to immediately retrieve and quarantine implicated components, for subsequent destruction	identify blood components *and plasma derivatives* from prior collections; notify consignee
diagnosed with other form of CJD	~~permanently defer~~ **indefinitely defer**	immediately retrieve and quarantine in-date...	do not withdraw pooled plasma, intermediates, and plasma derivatives	notify all consignees of implicated components...	identify blood components from prior collections; notify consignee
increased risk for CJD (dura mater transplant, human pituitary-derived growth hormone, one or more blood relatives diagnosed with CJD)	**indefinitely defer**, ~~and appropriately counsel~~	immediately retrieve and quarantine in-date...	do not withdraw pooled plasma...	notify all consignees of implicated components...	identify blood components from prior collections; notify consignee [except do not conduct tracing of prior donations for donor with CJD in only one family member]
risk for exposure to BSE (all geographic risk deferrals)	**indefinitely defer**	immediately retrieve and quarantine in-date...	do not withdraw pooled plasma...	notify all consignees of implicated components...	do not conduct tracing and notification of recipients of prior donations
received transfusion of blood or blood components in UK between 1980 and present	**indefinitely defer**	immediately retrieve and quarantine in-date...	do not withdraw pooled plasma...	notify all consignees of implicated components...	do not conduct tracing of prior donations...
injected bovine insulin since 1980, unless confirm that product was not manufactured after 1980 from cattle in UK	**indefinitely defer**	immediately retrieve and quarantine in-date...	do not withdraw pooled plasma...	notify all consignees of implicated components...	do not conduct tracing of prior donations...

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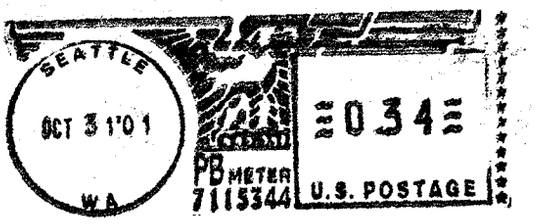

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