

August 29, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 02D-0266

Dear Dockets Management Branch:

We would like to submit comments regarding the Draft "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS);" Availability: July 2002. Specifically about Section IV, Subsection A, Number 8, which states: "[You should determine to be ineligible any donor who]; has injected bovine insulin since 1980, unless you can confirm that the product was not manufactured after 1980 from cattle in the U.K.."

**After gathering data from our donor records, we found that this recommendation will adversely affect the number of potentially transplantable corneas from our donor pool.**

We performed a retrospective donor chart review of all our donor charts (where eye tissue was procured) from the year 2001. The data is outlined below.

- 1099 donor charts were reviewed from the year 2001
- 865 donor histories met our initial criteria for transplant, of these:
- 147 donor histories included *any type of insulin use*
- 101 donor histories did **not** contain information that could clearly define the type of insulin used\*, thus these donors would be eliminated (not suitable for transplant)

\* Concerns: We determined that we could never assure with 100% certainty that these donors had never taken insulin manufactured from U. K. cattle, as we receive our information on insulin use from the donor's next-of-kin and from medical records (past and present) that are available to us. We often cannot obtain medical records that are more than a few years old (e.g. the records may have been placed in storage with limited access or they may have been destroyed). Another problem is that insulin has not always required a prescription for purchase; therefore, there is no way of knowing if the donor purchased a variety of brands. The one exception is donors who only received insulin during their final hospital visit. We did not include these donors, as we could definitely establish the type of insulin used.

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**Outcome for our eye bank: 101 donors (202 corneas) would have been eliminated from our 2001 donor pool. This is 11.7% of our 2001 donors.**

**Potential effect on U.S. cornea availability:** Per the 2001 Eye Banking Statistical Report, 84 U.S. eye banks reported a total of 41,960 donors and 46,532 corneas distributed for transplant use in 2001. We do not know how many of the donors met the transplant criteria for each eye bank, so we will use the number of corneas distributed for transplant to obtain a rough estimate of effect this recommendation could have on U.S. cornea availability. Using 46,532 corneas and two corneas per donor, we obtain 23,266 donors that met eye bank's transplant criteria. **If 11.7% of the 23,266 donors were ruled out due to insulin use (type unknown), then 2,722 donors or 5,444 corneas would be eliminated annually from the national donor pool.**

Such a reduction in available donors would have a detrimental effect on the supply of corneas available for transplant.

Since "no cases of transmission of vCJD have been reported in recipients of bovine insulin, or other injectable products manufactured in BSE-countries", we feel implementation of this recommendation would unnecessarily reduce the availability of corneas for transplant. This could have the result of people needing cornea transplants being put on waiting lists.

We appreciate the opportunity to comment to these proposed eye donor screening guidelines and your serious consideration of this data.

Sincerely,

  
Raylene Dale, Lab Manager

  
Donald J. Doughman, Medical Director

  
Jackie V. Mallin, Executive Director

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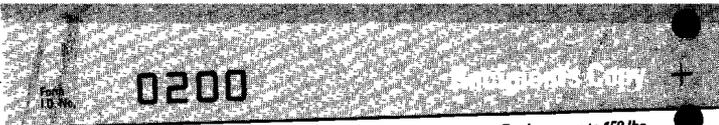
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