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Association of  
Organ Procurement  
Organizations

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August 13, 2004

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

Re: Docket No. 1997N-0484S

Dear Sir/Madam:

Thank you for the opportunity to comment on the May 2004 Draft Guidance document entitled *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*. The Association of Organ Procurement Organizations (AOPO) supports the Eligibility Guidance Document and its intent to increase the safety of tissues for transplantation.

AOPO is the private, non-profit, national organization representing all federally designated organ procurement organizations in the United States. The association mission is to provide advocacy, support, and development of activities that will maximize the availability of organs and tissues and enhance the quality, effectiveness, and integrity of the donation process.

The following comments have been developed by the AOPO Tissue Council, in consultation with other clinical working groups in the association.

**Section III.C.3, page 15**

**If they are available, the following other records also meet the definition of relevant medial records....FDA believes that examples of these records include: ...police records ...**

OPOs routinely do not pursue police records as available information. Questions exist regarding the access OPOs have to police reports even with the consent of the next of kin. Access to police reports is not included on consent forms. The utility to donation of information contained in police reports is uncertain.

How strongly will FDA look to OPOs to pursue police reports? Should an OPO know of the existence of a police report but not pursue the report, what documented rationale would FDA expect from the OPO for electing not to pursue the report?

**Section III.E.16, page19**

**FDA ... recommend[s] that you determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors ...**

**16. persons who have both a fever and a headache (simultaneously) during the seven days before donation (Ref. 8), we recommend that the donor be deferred from donation; ...**

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This section has the potential to exclude appropriate donors unnecessarily. In the absence of other risk factors for communicable diseases, are there circumstances when the presence of these two symptoms in a donor would be acceptable? For example, a donor with a subarachnoid hemorrhage may experience an elevated body temperature and headache simultaneously resulting from the presence of blood in the subarachnoid space.

**Section F.7, page 24**

**What clinical evidence do I look for when screening a donor?**

- 7. Sepsis (includes but not limited to bacteremia, septicemia, sepsis syndrome, systemic infection, or septic shock).**

**If bacteremia, septicemia, sepsis syndrome, systemic infection, or septic shock is specifically noted in the medical record, the donor is ineligible.**

Is it possible for FDA to consider revising this statement to indicate current "bacteremia, septicemia," etc.? The guidance document excludes the consideration of a donor who receives treatment for one of these conditions, with subsequent and appropriately-documented resolution, who expires from an unrelated event.

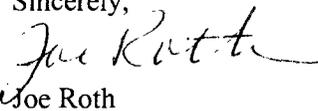
**Section IV.D, page 26**

**If a donor is one month of age or younger, from whom must I collect a specimen?**

The guidance document clarifies that a specimen must be collected from the mother. In the event that the mother is unavailable to the OPO within the 7-day period after donation and an appropriate maternal specimen is unavailable for testing, are there any circumstances under which an OPO may use a qualified specimen from the baby? Section F.2 page 28 specifies the testing methodology for pediatric donors. Are OPOs allowed to follow this process for a donor under one month in a circumstance where the mother is unavailable?

The Association of Organ Procurement Organizations appreciates your consideration of our comments. Please contact Jackie Coley, Chair of our Tissue Council (212-870-2240) or Paul Schwab, AOPO Executive Director (703-556-4242) should you have any questions or need additional information.

Sincerely,



Joe Roth

President

Association of Organ Procurement Organizations