



August 23, 2004

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

Dear Sir or Madam:

Thank you for this opportunity to offer comment on the draft entitled, "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products." As an association representing some 10,000 infection control professionals dedicated to preventing health care acquired infections across the continuum of care, we have a sincere interest in this issue.

As with any clinical situation, the risks of infection, injury, etc., need to be balanced against the potential benefit that may be realized by patients receiving these cells, tissues, and associated products. Overall, we commend the FDA for doing a fine job of providing a practical balance of those issues in this draft.

We offer the following specific recommendations for further enhancement of this document:

## **Section II. The Donor-Eligibility Determination**

H. It would be most helpful if FDA would clarify what we should do with the HTC/Ps before the donor-eligibility determination has been completed.

1. Also, is it acceptable to ship an HCT/P that is in quarantine?

There are very specific shipping container, labeling, etc., requirements for shipping potentially biohazardous materials. Obviously, we agree that all transporting/shipping of potentially biohazardous materials should be done in accordance with local and federal regulations, i.e., State and US Departments of Transportation, International Air Transport Association, etc.

#### **Section IV. Donor Testing: General (paragraph 1271.80)**

This section deals with many general aspects of donor testing, such as (A) who can perform the tests - a CLIA approved lab or equivalent; (B) what tests to use - FDA approved tests, etc. However, it would be most helpful if the document provided precautions and recommendations for properly and safely obtaining the samples to be tested. The tissue/cell harvesting business is relatively new. It is possible that personnel who would be obtaining tissues, body fluids or blood samples for testing may not inherently know that they must adhere to OSHA standards for bloodborne pathogens (using personal protective equipment [PPE], safe needle devices, etc). We would recommend that FDA consider including information about basic infection control precautions that one should take in the harvesting of this material.

We further recommend that CMV and rabies be included in the disease transmission section. CMV is mentioned in the latter part of the document, yet we know that it is routinely screened for in transplant work. Recent articles in the literature have also prompted increased vigilance with regard to rabies, so we would suggest its inclusion as well.

Again, we thank the FDA for this opportunity to provide input in the development of this important and timely document. If we may offer further assistance, please do not hesitate to contact Georgia Dash, Chair of the APIC Practice Guidance Task Force, at 215-707-4050 or [dashgp@tuhs.temple.edu](mailto:dashgp@tuhs.temple.edu) or Jennifer Thomas Barrows, APIC Director of Government and Public Affairs at 202-258-4644 or [jthomas@apic.org](mailto:jthomas@apic.org)

The Association for Professionals in Infection Control and Epidemiology (APIC) [www.apic.org](http://www.apic.org) is a nonprofit professional association comprised of more than 10,000 members whose responsibility is the prevention and control of infections and related adverse outcomes in patients and health care workers. APIC promotes wellness and prevents illness and infection worldwide by advancing health care epidemiology through education, research, collaboration, practice and credentialing. APIC's vision is to improve the health of people worldwide by serving as the preeminent voice for excellence in the prevention and control of infections and related disease outcomes.

Thank you for your kind consideration.

Sincerely,

A. Jeanne Pfeiffer  
2004 APIC President