

June 15, 2004

Food and Drug Administration  
Dockets Management Branch, HCFA-305  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

Subject: Draft Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, Docket No. 2004D-0193

Dear Sir or Madam:

On behalf of the Musculoskeletal Transplant Foundation (MTF), I am responding to the publication of the Draft Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products published in the Federal Register on May 25, 2004.

Founded in 1987, MTF is the nation's largest non-profit musculoskeletal tissue recovery organization and has recovered more than 35,000 tissue donors to date. The Foundation's membership consists of leading medical/academic/research institutions, as well as 31 tissue/organ recovery organizations throughout the country. The majority of these recovery organizations are OPOs that represent nearly 1/3 of the nation's total. The MTF is also an accredited member of the American Association of Tissue Banks (AATB) and has actively participated with the AATB to develop standards for tissue banking. We have formulated our comments to the draft guidance document based upon these experiences.

Speaking on behalf of MTF, we are encouraged by the FDA's approval of the Procleix HIV-1/HCV TMA NAT Assay for use in testing cadaveric blood samples. The use of NAT technology as a "supplemental test" for screening cadaveric tissue and cell donors will provide an additional level of safety for recipients. However, there are issues which we feel need to be brought to the agency's attention before a decision is made to require NAT testing for all tissue and cell donors.

Specifically, Section V. "Donor Testing: Specific Requirements" of the draft documents states:

*Nucleic Acid Testing (NAT): Although there are FDA-licensed NAT tests for HIV and HCV blood donor screening, these tests have not been validated for use with cadaveric blood specimens. FDA is working with industry to encourage development of NAT that is validated for use with cadaveric blood. As more information becomes available, FDA may recommend these tests for use in cadaveric tissue donors. FDA does recommend that living donors of HCT/Ps (e.g., hematopoietic stem/progenitor cell donors, semen donors) be tested with FDA-licensed NAT blood donor screening tests for HIV and HCV.*

**Musculoskeletal Transplant Foundation**  
A Nonprofit Organization

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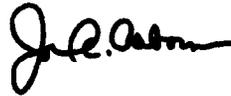
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For the past year, MTF has participated with Viomed Laboratories and Roche Laboratories with the development of Roche HIV-1 and HCV NAT PCR test for cadaver blood samples. Roche currently has an IND pending with the agency. It is important to note that MTF is not able to obtain an adequate specimen for HIV NAT testing in 5% of cases. In these cases, the tissue recovery facility is only able to supply a blood sample for the required serologic test. In some cases it is not possible to obtain enough volume of blood sample and in some cases the blood specimen has been collected in the wrong type of specimen tube or is not been handled appropriately. Despite working diligently with our tissue recovery organizations to obtain adequate blood samples for NAT testing, we have not been able to reduce the level below 5%. We believe that MTF's experience is probably not unique.

In 2005, MTF will recover tissue from approximately 4,800 donors. Therefore, approximately 240 (5% of 4,800 donors) will not have an adequate blood sample for NAT testing. We are working with Viomed on validating a NAT PCR test method for testing bone marrow samples from cadaver donors. Data from this initial study appear encouraging, but it will take quite some time to develop enough data that would be statistically significant.

We respectfully request that FDA not require NAT testing for tissue and cell donors until other sample sources can be evaluated and validated. We suggest that FDA continue to recommend NAT testing of tissue and cell donors as a "supplemental test"

Sincerely,



Joel C. Osborne  
Vice President of Quality Assurance and  
Regulatory Affairs

cc: Ruth Solomon – FDA CDRH  
Bruce Stroevever – MTF  
Robert Rigney – AATB