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May 17, 2006

James F. Burdick, M.D.  
Director, Healthcare Systems Bureau  
Health Resources and Services Administration  
Room 12C-06, Parklawn Building  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Burdick:

This letter provides comments from the American Society for Blood and Marrow Transplantation on the HRSA recognition of cord blood bank accreditation program(s) under Public Law 109-129, the Stem Cell Therapeutic and Research Act of 2005.

ASBMT is the national professional association of 1,400 clinicians, research investigators and allied health professionals that promotes advancement of the field of hematopoietic stem cell transplantation and cellular therapy.

Thank you for the opportunity to participate in the two conference call hearings this month. We had a representative at both. In this letter we wish to emphasize several points that, although touched upon in varying degrees in the hearings, are very important from the perspective of our members who will be selecting and transplanting the cord blood cells.

**Comprehensive Standards.** The standards for cord blood banks should be comprehensive. They should address all aspects of collection, processing, testing, banking, selection and release.

**International Recognition.** The standards should be internationally recognized. A search for cord blood knows no political boundaries. Already a significant proportion of units transplanted in the United States originates in other countries, and we expect that to grow. We need to know that units originating in other countries meet the same standards as units originating in the United States.

**Evidence-Based Science.** The standards should be based on evidence-based science, with emphasis on clinical outcomes of cord blood recipients. In areas where evidence is not available – which is not infrequent in this relatively new and growing field – the standards should be based on available evidence from pre-clinical studies and expert opinion. The standards should be regularly reviewed and updated.

**Cord Blood Bank Compliance.** We need to be confident that accredited cord blood banks are meeting the standards. This requires comprehensive on-site inspection of all aspects of cord blood processing, testing, storage and shipping, and regular audit and monitoring of the collection sites.

**Qualified Inspectors.** The accrediting agency must have highly qualified inspectors who are experts not only in cord blood banking but also the relevant laboratory sciences and the clinical aspects of cord blood

James F. Burdick, M.D.  
May 17, 2006  
Page Two

transplantation. There must be a comprehensive training program for inspectors that includes not only the inspection process, but also the preparation of accurate and timely inspection reports.

**Consistency.** Accreditation decisions should not be made in the field by inspectors. Accreditation decisions should be the outcome of a review of inspection reports by an accreditation committee that can equitably verify, document and consistently apply the standards and the accreditation criteria.

**Outcomes Evaluation.** A relevant, sophisticated system of measurement and reporting of clinical outcomes must be a part of the standards and the accreditation process. Every transplant procedure offers a new opportunity to learn and improve the therapeutic efficacy of cord blood transplants.

**Clinician Confidence.** The accreditation agency should be one that is familiar to, and has earned the respect of, the transplant coordinators and transplant clinicians who will be selecting the donor cells, transplanting them and monitoring the treatment outcomes.

**Professional Education.** The accrediting agency should have ready access to organizations that can help it with continuing education of clinicians, laboratory personnel and banking personnel – organizations such as ours, the International Society for Cellular Therapy (ISCT), the American Society for Hematology (ASH), the National Marrow Donor Program (NMDP) and The NetCord Foundation.

**Unified Implementation.** Undergirding all of the above is our conviction that there should be a single set of standards and a single accrediting agency. Multiple standards or multiple accrediting agencies are an invitation to inconsistency, confusion and increased administrative burden. We believe that a straight line can be drawn between variable standards or accreditation and variable quality and predictability of cord blood units. It also is only natural to expect cord blood banks to gravitate toward the accreditation that is perceived to be the easiest, least rigorous or least expensive. Multiple accreditation agencies would introduce a continuous struggle to equate standards and compare and contrast inspection and accreditation programs.

A physician preparing a patient for transplant has an enormous number of scientific, medical and patient care variables to consider. The quality of the cord blood unit should not be one of those variables.

In consideration of all the above, we unequivocally endorse FACT/NetCord to be the single recognized accrediting agency for the National Cord Blood Inventory. In our judgment, FACT/NetCord offers the significantly superior standards, inspection and accreditation program for assuring the safety and efficacy of units within the National Cord Blood Inventory.

We will be happy to respond to any questions. Thank you again for the opportunity to offer our comments and recommendations.



Sincerely,  
Robert Negrin, MD  
President

cc: ASBMT Board of Directors