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A Division of the New York Blood Center
Placental Blood Program

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May 8, 2001

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Ref. Docket No. 97N-484P: Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-based Products: Inspection and Enforcement.

Gentlemen:

I write as the Director of the Placental Blood Program of the New York Blood Center. This Program was initially established in 1992, with funding from NHLBI, to test the feasibility of using Placental/Umbilical Cord blood as a source of hematopoietic stem cells for transplantation into unrelated recipients. The Program developed standards for the collection, processing, testing, cryoprotection, freezing and storing cord blood units for eventual selection by bone marrow transplant physicians in recognized Transplant Centers. Since 1996 the Program has worked under an IND exception from FDA (BB IND 6637). During its life, the Program has collected close to 14,000 cord blood specimens and issued over 1100 cord blood units to patients in over 140 transplant centers worldwide. Over 1070 of these have been already transplanted.

During this time numerous other groups in the US, Europe, Japan and elsewhere have started similar Programs. Many of them are directed by reputable individuals and are under at least some regulatory supervision, their respective Standards are different. A number of these Banks have also provided excellent grafts to patients in the US and others may do so in the near future. Not all Banks, however, have provided equally acceptable transplants and patients may have suffered as a consequence. Recent efforts from FAHCT and NETCORD to provide an international set of Standards for cord blood banking notwithstanding, the definition of thorough rules for Good Tissue Practice by the US FDA adds, in my opinion, a necessary ingredient to the protection of transplant recipients.

The rules contained in proposed new Part 1271 (title 21 CFR) represent an exhaustive effort to identify all or most of the elements that can be used to document compliance with current Good Tissue Practices. I believe the proposed rules are reasonable and will help assure the safety of use of such grafts for

transplant recipients. Clearly, our Program will need to implement more rigorous documentation procedures and will make the necessary personnel investment.

I do have a minor suggestion with respect to subpart 350, which deals with Reporting. The proposed rule indicates the responsibility to report by "Any establishment that receives information about an adverse reaction." In fact, given the need to investigate all cases in which an adverse event may conceivably be due to a noxious effect of the graft, it might be important to specify the need to facilitate, encourage and even solicit this information by the cord blood Banks themselves. In fact, the probability of receiving such information in some cases may be determined in part by the presence of absence of a well-defined active follow-up program implemented by the Bank.

Respectfully submitted,

Pablo Rubinstein

Pablo Rubinstein, M.D.
Director
Placental Blood Program,
New York Blood Center

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