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March 25, 1996

David A. Kessler, MD
Commissioner of Food and Drugs (HF-1)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket #96N-0002

Dear Dr. Kessler:

We are aware of the pending draft policy statement concerning the regulation of umbilical cord blood banking. We are concerned that while regulation is necessary to assure the safety and quality of these cord blood stem cells, the proposed call for IND level regulation will be excessively restrictive.

Families with history of Fanconi anemia are very encouraged by the early successes of umbilical cord blood transplants as a potential curative therapy for this historically fatal disorder. Parents of children with Fanconi anemia want access to the cord blood of their own newborn as a potential cure for a sick child. Cord blood should be collected as part of the birthing event by attendant obstetricians and midwives. The precious collection must be handled with utmost care and delivered without delay to a qualified facility which operates at the highest level of standards for processing blood products for clinical use. Only recently has access to this kind of service been made possible for families with Fanconi anemia.

We are aware of the NIH funded, cord blood donor bank program and support this kind of effort to improve the availability of unrelated donor stem cells in this country. However, we are convinced that guaranteed access to a family source of stem cells is preferable for those who are burdened with genetic diseases such as Fanconi anemia. The NIH grant recipients generally are not positioned to provide a family specific service, but rather to process donated cord blood for unrelated allogeneic use.

Requiring an IND for cord blood will impede providers of family cord blood banking service from making their service widely available and possibly put them out of business. Afflicted families would be unable to arrange for collection of cord blood for sibling cord blood transplants.

We strongly urge you to consider all the consequences of your regulatory strategy, intentional and unintentional, before the policy is made final. We support the need to regulate to the extent that the law does not deny access to life-saving and cost effective medical solutions.

Sincerely,

Joyce Owen, PhD, President
Board of Directors

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Sent to
Mr. Donnelly
2/27/96