



NEW JERSEY
MEDICAL SCHOOL

University of Medicine & Dentistry of New Jersey

June 18, 2010
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Attn: Deborah Autor, Director of Office Compliance

Dear Deborah Autor,

A few years ago you advised me that cord blood transfusions minimally manipulated (treated as routine blood transfusion) could not be used for neurological diseases, ALS, Huntington disease, neurological trauma, diabetes 1 and 2 etc. without an IND.

We are trying to setup cord blood transfusion for the neurological wounded in Afghanistan and Iraq. As far as we know cord blood transfusion have been safe or safer than adult blood transfusion as far back as 1914 (1) and 1918 (2).

My previous inquiries to you on this matter as to medical use of cord blood transfusion without bone marrow replacement required an IND, but an explanation was not provided by the FDA, only that it was their regulations.

Could you provide this explanation if your restrictions still persist?

We anticipate significant increase in casualties, particularly neurological, in Afghanistan in the near future. We would appreciate a response as soon as possible.

Sincerely,

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References:

1. Rubin, G., *Placenta blood for transfusion*. New York Med J, 1914. **100**: p. 421.
2. Goodall AF, Jr, Altimas, GT & MacPhail, FL. 1938. *An inexhaustible source of blood for transfusion and its preservation*. Surgery, Gynecology and Obstetrics, **66**:176-178.

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