Stem Cell Therapeutic and Research Act of 2005

(Smith Stem Cell Bill)

This ground breaking legislation will transform medical treatment by making genetically matched cord blood stem cells available to patients who need them. Cord blood stem cells are already treating patients, and this legislation will provide new opportunities for patients to access cures. It is critical that this resource be made widely available because of the rapidly growing number of devastating diseases which could be addressed through cord blood stem cell research and treatments.

Background:

Umbilical cords are a rich, non-controversial source of stem cells, but currently hospitals throw millions of them away each year. These stem cells can be matched to patients and have already been used to treat thousands of patients of more than 67 diseases, including Leukemia, Sickle Cell Anemia and Hurler disease. In addition, published studies have shown that cord blood stem cells have the capacity to change into other cell types, which give them the potential to treat many fatal, terminal and debilitating conditions, including spinal cord injury, Parkinson's, diabetes and heart disease.

Bill Summary (cord blood section):

Inventory – The cord blood stem cell portion of this bill will provide federal funding to increase the number of cord blood units available to match and treat patients. The goal is to reach a total inventory of 150,000 units so that matched stem cells will be available to treat more than 90% of patients, especially focusing on providing genetic diversity.

Coordinated Search - The legislation would also link all the cord blood banks participating in the inventory program into a search system that would allow transplant physicians to search for cord blood and bone marrow matches through a single access point.

Research - The national program would promote stem cell research by requiring any participating cord blood banks to donate units, not suitable for transplant because of disease or size, to researchers who are working on new applications for cord blood stem cells.

Program Structure – C.W. Bill Young Transplantation Program with an Advisory Council appointed by the Secretary of HHS, with a separate cord blood function and a separate bone marrow function.

Funding - \$79 million over 5 years - FY 06 \$19 million, FY07-FY10 \$15 million each

Reauthorizes the Bone Marrow Program - The National Bone Marrow Registry authorization expired on September 30, 2003. The bill reauthorizes an updated program through fiscal year 2010 for \$28 million in FY06 and \$32 million each additional year. The bone marrow functions include many of the provisions passed by the House in the 108th Congress.

Cord Blood is Already Treating Patients

• This link has a list of **67 diseases** that one cord blood center has already treated with cord blood stem cells: <u>http://www.nationalcordbloodprogram.org/patients/ncbp_diseases.htm</u>. In addition, this link has some of the patient stories, including patients who where successfully treated **for Sickle Cell Disease, Leukemia, Osteopetrosis, Diamond Blackfan Anemia, and Adrenoluekodystrophy**:

 $\underline{http://www.nationalcordbloodprogram.org/patients/patients_stories.html}\,.$

- **Spinal Cord Injury** last October, a Korean woman who had been paralyzed for 19 years took a few steps for reporters in Seoul with the aid of a walker roughly a month after doctors injected cord blood stem cells in her spine. http://times.hankooki.com/lpage/tech/200504/kt2005041818233411800.htm
- Neurological Diseases Cord blood from unrelated donors was used to treat Krabbe's disease in infants, before the symptoms developed, and most of the children treated were cured and achieved age-appropriate cognitive development; without treatment this disease leads to severe neurological deterioration and death. http://content.nejm.org/cgi/content/short/352/20/2069
- Cord blood transplants do not need to be a perfect match, so it is easier to match the treatment to the patient.
- **Cord blood works for adults** (November 28, 2004, New England Journal of Medicine), leading Nelson Chao, MD, Head of the Adult Marrow Transplant Program at Duke University, to declare "Cord blood is now ready for prime time." (American Society for Hematology, December 2004).
- 150,000 cord blood units would provide all patients an 80-90% chance of finding a 5 of 6 HLA match (and a 6 of 6 for about 30%) (based on an analysis of the New York Blood Center experience).
- **Cord blood is frozen and ready to go.** When a suitable cord blood unit is found, it is guaranteed to be available and can be dispatched to a patient within one week (24 hours in an emergency).
- Minority patients, and others with rare tissue types, benefit from cord blood as a source of stem cells since matches do not have to be perfect. African-Americans constitute 19% of the 1,276 US patients who have gotten cord blood transplants from the New York Blood Center's Program, for example.

Cord Blood - Incredible Potential for Additional Treatment and Research

Cord blood stem cells have the capacity to change into other cell types, which give them the potential to help regenerate organs and treat many fatal, terminal and debilitating conditions, including spinal cord injury, Parkinson's, diabetes and heart disease.

- **Cord Blood Stem Cells have the potential to become any cell type in the body.** Human Cord Blood stem cells show pluripotent (can become any type of cell in the body) potential and extensive proliferation - Kögler G *et al.*, "A new human somatic stem cell from placental cord blood with intrinsic pluripotent differentiation potential", *J. Experimental Medicine* 200, 123-135, 19 July 2004
- Cord Blood Stem Cells can turn into other types of cells and reproduce in a Petri dish for research. Cord blood stem cells that can turn into different types of cells are already available to researchers and medical companies with an interest in regenerative medicine and drug development. These research lines have already been turned into tissues representative of the three germinal layers, including neural stem cells, nerve cells, liver/pancreas precursors, skeletal muscle, fat cells, bone cells and blood vessels http://www.genengnews.com/news/bnitem.aspx?name=519610XSL_NEWSML_TO_NEWSML_WEB.xml