

# Update on The HHS Advisory Council on Blood Stem Cell Transplantation

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U.S. Department of Health and Human Services (HHS),  
Health Resources and Services Administration (HRSA),  
Division of Transplantation, Blood Stem Cell  
Transplantation Program

# The Stem Cell Therapeutic and Research Act of 2005: Overview

- **Public Law 109-129**
- **Signed December 20, 2005**
- **Aims are to increase:**
  - **Number of unrelated donor transplants**
  - **Public Inventory of high quality CBU from diverse populations**
  - **Number of CBU available for research**

# The Stem Cell Therapeutic and Research Act of 2005: Overview (cont'd)

- **Key Elements of New Law:**
  - National Cord Blood Inventory to collect high quality CBU from Diverse populations for use in unrelated-donor transplant; target of 150,000 new units
  - C.W. Bill Young Cell Transplantation Program to facilitate transplants with cells from cord blood and bone marrow, collect data on transplant outcomes
  - Establishment of the new HHS Advisory Council on Blood Stem Cell Transplantation for these programs
- **Opportunity to help more patients obtain transplants, other therapies**

# Establishment of Advisory Council on Blood Stem Cell Transplantation

- Purpose:
  - Consider and make recommendations to the Secretary of HHS, and HRSA, on matters related to the C. W. Bill Young Cell Transplantation Program
- Advisory Council charter published in the *Federal Register* on January 23, 2007 with nominations for membership solicited by February 22, 2007
  - Over 100 nominations of highly qualified candidates received by HRSA

# Advisory Council Membership

- Consisting of up to 25 voting members, the law requires reps from:
  - Marrow donor and transplant centers
  - Cord blood banks
  - Birthing hospitals
  - Blood stem cell recipients/ family members

# Advisory Council Membership (cont'd):

- Persons with expertise in blood stem cell transplantation (Cord blood & Bone Marrow)
- Persons with expertise in typing, matching, and transplant outcome data analysis
- Persons with expertise in the social sciences
- Basic scientists with expertise in the biology of adult stem cells
- Members of the general public

# Ex-Officio (Non-voting) Members

- Department of Defense Marrow Donor Program operated by the Dept. of Navy
- Division of Transplantation of HRSA
- FDA
- NIH
- CDC
- CMS

# Possible Topics for Advisory Council:

- Targets for National Cord Blood Inventory & Adult Registry-size & composition
- Research Priorities
  - HPC transplantation
  - Other therapy with cells from CB & BM
  - Criteria for releasing units for research
- Informed Consent Requirements
- Accreditation Recommendations



## Possible topics, *cont'd*

- Confidentiality Issues
- Key CBU Characteristics that Improve Outcomes
- Criteria for recommending specific stem cell sources for varying diagnoses, demographics, and clinical conditions
- Public & Professional Education - re donation
- Strategies and resources to expand opportunities for eligible pregnant women to publicly bank their infants' CBU

## Possible topics, *cont'd*

- Regulatory Policy – including international harmonization of regulation and importation issues
- Public and Private Insurers – actions to increase donation and access to transplant
- State and Federal Government - actions (other than as insurers) to increase donation and access to transplant

## Advisory Council, cont'd

- Status of Council as of this meeting:
  - Nominations are under review in the Department
  - Uncertain when appointments by the Secretary will be made
  - A Meeting Logistics contract has been awarded to support the Council
  - We are prepared to hold first meeting late fall 2007

# References

- Stem Cell Therapeutic and Research Act of 2005 (P.L. 109-129)
  - [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109\\_cong\\_public\\_laws&docid=f:publ129.109.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ129.109.pdf)
- IOM Report
  - <http://www.iom.edu/CMS/3740/20073/26386.aspx>
- National Cord Blood Inventory, 2<sup>nd</sup> Cohort Request for Proposals
  - <http://www1.fbo.gov/spg/HHS/HRSA/DGPM/07%2DN234%2D5765%2Ddm/listing.html>
- *Federal Register* notice: Establishment of the Advisory Council on Blood Stem Cell Transplantation
  - [http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=2892&dbname=2007\\_register](http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=2892&dbname=2007_register)

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