The Joint Subcommittee to Study the Medical, Ethical, and Scientific Issues Relating to Stem Cell Research Conducted in the Commonwealth

Federal and State Cord Blood Legislation

Federal Legislation:

On December 20, 2005, the President signed into law:

H.R. 2520, the "Stem Cell Therapeutic and Research Act of 2005", which creates a new Federal program to collect and store cord blood, and expands the current bone marrow registry program to also include cord blood.

The bill authorizes \$79 million in federal funding for the collection and storage of umbilical cord blood

The following states have hospitals that participate in the National Marrow Donor Programs' Cord Blood Bank Network:

Alabama California Florida Hawaii Illinois Michigan Missouri New Jersey North Carolina Ohio Texas Washington

Currently, Virginia is not a part of the network, and thus is not eligible for this federal funding. Virginia's language specifies that the Initiative is a statewide effort for all Virginians.

State Legislation:

Legislation to educate expectant mothers about umbilical cord blood banking:

Arizona: Beginning in 2007, health care professionals must inform pregnant women about ability to donate, and benefits of donation to the newborn and immediate family members. First state to include information on free cord blood collection and storage programs offered by

family or sibling donor banks (for families with children who have conditions treatable with stem cells).

Florida, Illinois, Maryland, New Mexico, Wisconsin: All require that pregnant women be notified of opportunity to donate.

Virginia: No requirement to reach all pregnant women. Language is permissive.

Education/awareness programs for the public (benefits of donation, etc):

Georgia: Actually established by Executive Order when legislature failed to act before the end of session.

California, Massachusetts, New Jersey, New Mexico, South Dakota, Virginia: Programs to educate the public about the benefits of cord blood collection, also, in many states, as to the difference between public and private donation (**NOT in Virginia**).

Establishing public cord blood banks:

Oklahoma: Established advisory council to consider developing cord blood donor program.

Massachusetts, Ohio, New Jersey, Missouri, Texas, Virginia: Established banks, or provided funds to aid development of banks. Missouri establishes the Life Sciences Research Board, which will establish program to distribute grants to assist in development of cord blood banks, or to help expand existing banks.

Structure of the Program described in 2005 H.R. 2520

The NY Blood Center (<u>NYBC</u>) and the National Marrow Donor Program (<u>NMDP</u>) reached a compromise in the quest for a national cord blood registry: On 24 May 2005, the House of Representatives passed, by a vote of 430 to 1, the bill H.R. 2520 "Stem Cell Therapeutic and Research Act of 2005". This bill is a marriage between the stalled NMDP re-authorization (HR 3034) and the NYBC proposal for a national cord blood program (HR 596). HR 2520 was passed under a <u>suspension of rules</u> which only occurs if there is prior agreement by interested parties. The full text of HR 2520 can be read in the Congressional Record at <u>thomas.loc.gov</u>:

- HR 2520 allocates \$79 million to compile a national inventory of 150,000 highquality cord blood units for transplantation.
- Collected cord blood which is not suitable for transplantation will go to peerreviewed research.
- The National Cord Blood Program is now renamed the C.W. Bill Young Cell Transplantation Program. This name is associated with the <u>DoD branch of the NMDP</u>.
- The Dept of Health and Human Services (HHS) will contract directly with banks for bone marrow and/or cord blood services.
- The bone marrow and cord blood programs will be at the same administrative level, and may be under one contract or two.
- This effectively means that patients will have one-stop shopping for stem cell transplants.
- The cord blood contract must be competed during the first year and qualifying banks must be willing to enlist for 10 years.
- Qualifying cord blood banks must comply with <u>section 379 of the Public Health</u> <u>Service Act</u>. This was the 1998 legislation authorizing the NMDP registry. It remains to be seen if cord blood banks in the national registry will have to comply with current NMDP protocols for "participating" cord blood banks.
- There will also be a contract for collection of transplant outcomes data, like the work performed by <u>CIBMTR</u>.
- An advisory committee will oversee all forms of hematopoietic stem cell transplants.
- Within 6 months of the enactment of this program, the committee must define what is a "high-quality" cord blood unit.
- These compromises partly follow the recommendations of the Institute of Medicine report, but push the cord blood program into parallel with the current bone marrow program.
- At present, HHS has \$19 million to start spending on cord blood collection, even though this legislation is still pending in the Senate.