

CORD BLOOD STEM CELL BANKS AND RESEARCH

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House Bill 6291 as passed by the House
Sponsor: Rep. Glenn Steil, Jr.

House Bill 6292 as passed by the House
Sponsor: Rep. Jacob Hoogendyk, Jr.

House Bill 6293 as passed by the House
Sponsor: Rep. Leslie Mortimer

House Bill 6295 as passed by the House
Sponsor: Rep. David Law
Committee: Health Policy

House Bill 6294 as passed by the House
Sponsor: Rep. Tom Casperson
Committee: Appropriations

Revised First Analysis (11-28-06)

BRIEF SUMMARY: House Bill 6291 would establish a network of cord blood stem banks. House Bill 6292 would establish a tax credit for donations of cash and cord blood to cord blood stem cell banks. House Bill 6293 would increase awareness and public knowledge about the network of cord blood stem cell banks and the benefits of cord blood stem cells. House Bill 6294 would appropriate \$5 million of 21st Century Jobs Trust Fund monies to be used to support a statewide network of cord blood stem cell banks. House Bill 6295 would allow cord blood stem cell banks to apply for 21st Century Jobs Fund grants.

FISCAL IMPACT: The bills would have a fiscal impact on the state. See a detailed fiscal analysis below.

THE APPARENT PROBLEM:

Both adult stem cells and embryonic stem cells hold great promise in providing treatments for many diseases because, unlike a nerve cell or liver cell which always stays the same, stem cells can develop into any type of cell. Adult stem cells are found in many tissues in the body, for example, in bone marrow, but are found in abundance in the leftover blood in an umbilical cord after a baby is born. Umbilical cord blood stem cells are processed and stored and transplanted to treat about 70 different diseases, including blood cancers, Parkinson's, multiple sclerosis, sickle cell anemia, and brain cancer. Currently, 20 hospitals in the state collect donated umbilical cords for use by public cord blood banks. Two of the 14 cord blood banks in the nation that are part of the National Marrow Donor Program are located in Michigan. Some feel that if donations of cord blood increased, there would be greater access to treatment, improved outcomes for

patients, and the ability to conduct state-of-the-science research that could lead to cures for certain cancers and other genetic diseases. Legislation intended to spur increased donations and research has been offered.

THE CONTENT OF THE BILLS:

Together, the bills would establish a network of cord blood stem cell banks; provide a tax credit for cash donations to the network of cord blood stem cell banks and for donations of cord blood to a cord blood stem cell bank; promote awareness of the network of cord blood stem cell banks and benefits of the uses of cord blood stem cells; and include "umbilical cord blood" as one of the technologies classified as "biotechnology" in the definition of "life sciences," which would make proposals involving cord blood stem cells eligible for funding under the 21st Century Jobs Trust Fund initiative. A more detailed description of each bill follows:

House Bill 6291

The bill would add a new section to the Public Health Code (MCL 333.2682) to require, if funding were made available, the Department of Community Health to establish a statewide network of cord blood stem cell banks. The DCH director would have to enter into contracts with qualified cord blood stem cell banks to assist in the establishment, provision, and maintenance of the network.

Entry into the network. To be eligible to enter the network and be a donor bank, a cord blood stem cell bank would have to satisfy each of the following:

- Obtain all required applicable federal and state licenses, accreditations, certifications, registrations, and other authorizations.
- Implement donor screening and cord blood collection practices adequate to protect donors and transplant recipients and to prevent transmissions of potentially harmful infections and other diseases.
- Establish confidentiality practices to protect the identity and privacy of patients and donors in accordance with federal and state law and consistent with HIPPA regulations for the release of the identity of donors, recipients, or identifiable records.
- Establish a system for encouraging donation by an ethnically and racially diverse group of donors.
- Develop adequate systems for communication with other cord blood stem cell banks, transplant centers, and physicians regarding the request, release, and distribution of cord blood units nationally. The systems would have to be consistent with HIPPA regulations promulgated to track recipients' clinical outcomes for distributed units.
- Develop an objective system for educating the public about benefits of donating and utilizing cord blood stem cells in appropriate circumstances.

Responsibilities of a donor bank entering the network. Each donor bank entering the network would have to acquire, tissue-type, test, cryopreserve, and store donated units of human cord blood in compliance with applicable federal regulations; make cord blood units collected under the bill's provisions available to transplant centers for stem cell transplantation; and allocate up to ten percent of the cord blood inventory each year for peer-reviewed research. The quota allocated for this research could come from cord blood units which did not meet cell count standards necessary for transplantation.

Board of directors. The bill would require a board of directors to govern and administer the state cord blood stem cell bank network. It would be composed of the DCH director and members appointed by the governor who represent each of the following: cord blood stem cell transplant centers, physicians from participating birthing hospitals, the cord blood stem cell research community, recipients of cord blood stem cell transplants, family members who have made a donation to a statewide cord blood stem cell bank, individuals with expertise in the social sciences, members of the general public, and each network donor bank. The duration of the initial terms would be staggered from one to three years, after which time appointments would be for three-year terms.

The board would have to elect a chairperson. The board would be required to ensure that the donor banks within the network meet the requirements of being in the network on a continuing basis; encourage network donor banks to work collaboratively with other network donor banks and encourage network donor banks to focus their resources in their respective local or regional area; designate one or more established national or international cord blood registries to serve as a statewide cord blood stem cell registry; and coordinate the donor banks in the network.

The bill is tie-barred to House Bill 6293 and Senate Bill 1353, which would amend the Public Health Code to define terms, including "donor" and "cord blood unit."

House Bill 6292

The bill would add a new section to the Income Tax Act (MCL 206.272) to create a tax credit for individuals making a cash donation or donating cord blood to a cord blood stem cell bank. For tax years that begin after December 31, 2006, a taxpayer could claim a credit against the tax imposed by the act equal to 50 percent of the sum of the following, not to exceed \$100 for a single filer or \$200 for a joint filer:

- Cash donations made to the statewide network of cord blood stem banks established by the provisions of House Bill 6291; and
- Cash donations made to a qualified cord blood stem cell bank in the network.

In addition to the credit allowed above, a taxpayer who made a donation of cord blood to a cord blood stem cell bank under the provisions of House Bill 6291, for tax years beginning after December 31, 2006, could claim a tax credit equal to \$100 in the year of the donation. "Cord blood" would mean blood collected from the separated placenta or umbilical cord immediately after birth.

If the taxpayer banked cord blood in a private cord blood stem cell bank, and the cord blood was used exclusively for the taxpayer or a member of his or her family, the taxpayer could claim a credit – for tax years beginning after December 31, 2006 – equal to \$100 in the year of the donation. This credit would not apply if the taxpayer banked cord blood as part of a designated free blood collection and storage program. "Family member" would mean a donor child or a relative within the second degree of consanguinity to the donor. "Private cord blood stem cell bank" would mean a nongovernmental nonpublic cord stem cell bank that was both registered with the Federal Drug Administration (FDA) and accredited by the American Association of Blood Banks.

If the amount of the credit allowed under the bill exceeded the tax liability of the taxpayer for the tax year, that portion of the credit that exceeded the tax liability would have to be refunded.

The bill is tie-barred to House Bill 6291.

House Bill 6293

The bill would add a new section to the Public Health Code (MCL 333.2683) to require the Department of Community Health to develop and disseminate educational materials on the uses and benefits of cord blood cells, information on research results utilizing cord blood stem cells, and any other related materials and information to enable the public to make informed decisions about the utilization of cord blood stem cells. The purpose would be to promote public awareness and increase public knowledge about the statewide network of cord blood stem cell banks, cord blood banking options, and the benefits of cord blood stem cells,

Information and materials gathered and developed would have to be made available by the DCH to the public through the department's website. The department would have to provide each health facility or agency, cord blood bank, and health care professional copies of the same information upon request at no charge. The department would also have to encourage health care professionals and health care facilities or agencies, including birthing facilities, local health departments, physicians, nurse midwives, and nurses, to disseminate information to pregnant women about cord blood bank donation and the options for cord blood banking.

The bill is tie-barred to House Bill 6291 and Senate Bill 1353.

House Bill 6294

House Bill 6294 would appropriate \$5 million of 21st Century Jobs Trust Fund monies to the Department of Treasury, Michigan Strategic Fund, as a supplemental appropriation for Fiscal Year 2005-06, to be used to establish and support a statewide network of cord blood stem cell banks. The bill would direct the Department of Treasury to distribute the funds to the Department of Community Health (DCH) to administer the initiative. The funds would be expended by DCH for grants and contracts with qualified cord blood

stem cell banks, promotion and state administration of the network, and to increase awareness and knowledge about the benefits of cord blood stem cell research. The funds could not be used for any fixed capital costs.

Boilerplate in the bill states that this appropriation would be authorized as part of the \$400 million bond proceeds from the tobacco securitization bonds deposited to the 21st Century Jobs Trust Fund. Boilerplate also establishes the funds as a work project appropriation under which any unencumbered or unallotted funds may be carried forward into future fiscal years for this initiative. The bill states that if the funds are carried forward, DCH would be responsible for expending the funds as provided in this act. The bill would require a report from the Department of Community Health on the expenditure of the funds.

House Bill 6295

The bill would amend the Michigan Strategic Fund Act (MCL 125.2088a). The act defines the term "life sciences" as science for the examination or understanding of life or life processes, including, but not limited to, bioengineering, biomedical engineering, genomics, proteomics, molecular and chemical ecology, and biotechnology. "Biotechnology" includes any technology that uses living organisms, cells, macromolecules, microorganisms, or substances from living organisms to make or modify a product for useful purposes. The bill would include in the definition of "biotechnology" umbilical cord blood.

(Recently enacted legislation that created the 21st Century Jobs Fund allows the fund to be used to provide loans, grants, and investments in the stock of private companies to entities producing products or services in any of four competitive edge technologies: life sciences, alternative energy sources, homeland security, and advanced manufacturing and materials. The fund consists of the proceeds of the sale of a portion of future tobacco settlement receipts.)

FISCAL INFORMATION:

House Bill 6291 and House Bill 6293 have fiscal implications for the Department of Community Health (DCH).

House Bill 6291 as substituted has fiscal implications for the Department of Community Health. The bill requires the Department of Community Health to establish a state network of cord blood stem cell banks, evaluate initial and continuing eligibility of banks that wish to participate, establish a board of directors to govern and administer the network. This function will require a Department financial commitment for staff and governing board costs, on an ongoing basis.

House Bill 6293 as substituted has fiscal implications for the Department of Community Health. The bill requires the Department of Community Health to educate and inform the public, health care facilities, and health care professionals about the statewide network of

cord blood stem cell banks, and the use of cord blood stem cells and banks. This function will require a modest Department financial commitment for staff and publication and distribution costs, on an ongoing basis.

House Bill 6292 would result in an indeterminate reduction in income tax revenue.

House Bill 6294, as a supplemental appropriation, effectively provides \$5.0 million of 21st Century Jobs Trust Fund monies through the Michigan Strategic Fund to the Department of Community Health for establishment of a statewide network of cord blood stem cell banks. This is a one-time fund source from the proceeds of the tobacco securitization bond issuance, appropriated in FY 2005-06. As of September 13, 2006 when the House passed the bill, all but \$70.6 million of the \$400.0 million bond proceeds was allocated and awarded. As of November 21, 2006, \$34.6 million remained unallocated following a late September announcement of grant awards. Enactment of this bill will establish that \$5.0 million of the amount yet unallocated as of the date of enactment is to be used to fund this project, which may be carried forward into FY 2006-07.

Michigan currently has two cord blood stem cell banks. Data provided by the banks indicates a cost of \$1,000 to process and store one cord stem cell unit.

House Bill 6295 would have no fiscal impact on the State of Michigan or its local units of government.

ARGUMENTS:

For:

Harvesting adult stem cells from umbilical cord blood should be supported for the following reasons:

- Unlike embryonic cells, harvesting adult stem cells from umbilical cord blood does not result in the destruction of an embryo and the cells are already used to treat about 70 diseases (embryonic stem cell research has yet to produce a successful treatment for any disease).
- Unlike bone marrow, a donor and a recipient of cord blood stem cells do not have to be as exact of a match for successful transplantation. This is especially important for minorities, whose ancestry is not as homogenous as for Caucasians.
- Harvesting stem cells from cord blood is not an invasive procedure and so carries no risk to mother or baby.
- Umbilical cords are classified as medical waste; if not donated to a public or private cord blood bank, they are incinerated.

For:

Reportedly, more hospitals in the state are interested in collecting donated cord blood for the cord blood banks, but lack funding to do so. There also is a need to educate the public about the need for cord blood donations and the benefits of cord blood treatments.

Enabling the creation of more cord blood banks and earmarking a minimum amount of cord blood stem cells for research would attract medical researchers and scientists and ensure that Michigan is a repository of cutting edge medical research. The bill package would accomplish these goals by educating the public about the benefits of cord blood treatments and the need for cord donations, encouraging donations of cords for public use and cash gifts to support cord blood research through tax credits, enable cord blood banks to be eligible for 21st Century Jobs Trust Fund monies, appropriate money from the trust fund to support the establishment of cord blood banks and cord blood research, and establish standards for cord blood banks and the statewide network of cord blood banks. The legislation is good public policy and should be supported.

Against:

Some are concerned that enactment of the legislation would have a chilling effect on embryonic stem cell research. Many researchers feel strongly that embryonic stem cell research holds a greater promise for effective treatments to treat and prevent many diseases and repair spinal and other injuries. Just because adult stem cells have yielded earlier treatments doesn't mean that those treatments are more effective or desirable. Many in the medical and scientific communities believe that the answers to treat many serious diseases and injuries are not exclusive to one source of stem cells.

The question should also be asked if the 21st Century Jobs Trust Fund is an appropriate source to fund the objectives of the bill package. Most of the monies have already been appropriated or earmarked for specific projects. The remaining funds, about \$34 million, were supposed to be awarded in the form of grants during the 2007 fiscal year. Or, since House Bill 6294 was not enacted by the close of the 2006 fiscal year, some wonder if it is still possible to appropriate money from the trust fund.

Response:

Medical research absolutely fits within the goals of the Michigan Strategic Fund Act and the 21st Century Jobs Trust Fund. Expenditure of the funds appropriated by House Bill 6294 would create jobs, attract the top minds in the fields of genetic and medical research, and provide life-saving medical procedures to people around the world. Also, though appropriations generally must be enacted prior to the close of a fiscal year or at least by the book closing (which typically happens in late December), there is established precedent to utilize supplemental appropriations to fund projects in a given fiscal year even after the close of that fiscal year.

POSITIONS:

A representative of the Michigan Department of Community Health testified in support of the bills. (9-29-06)

A representative of the Michigan Community Blood Centers testified in support of the bills. (9-12-06)

A representative of Right to Life of Michigan testified in support of the bills. (9-20-06)

A representative of the Michigan Health & Hospital Association (MHA) testified in support of the bill. (9-12-06)

A representative of the Karmanos Cancer Institute submitted testimony in support of the bills. (9-12-06)

Michigan Catholic Conference indicated support for the bills. (9-12-06)

St. John Health indicated support for the bills. (9-12-06)

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■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.