# Department of Legislative Services

Maryland General Assembly
2006 Session

## FISCAL AND POLICY NOTE
**Revised**

Senate Bill 144 (Senator Hollinger, *et al.*)

Education, Health, and Environmental Affairs and Budget and Taxation — Health and Government Operations and Appropriations

**Maryland Stem Cell Research Act of 2006**

This bill creates a Maryland Stem Cell Research Fund to promote State-funded stem cell research and cures through grants and loans to public and private entities in Maryland. Annually, beginning in fiscal 2008, the Governor may include in the budget bill an appropriation to the stem cell research fund. An independent Stem Cell Research Commission is also established under the Maryland Technology Development Corporation (TEDCO). An independent scientific peer review committee will evaluate stem cell research proposals for the commission. An applicant for State-funded stem cell research must first obtain an institutional review board's approval before receiving funding.

The bill takes effect July 1, 2006.

## Fiscal Summary

**State Effect:** No effect in FY 2007. General fund expenditures could increase significantly beginning in FY 2008 if the Governor includes an appropriation in the annual budget bill for the stem cell fund.

**Local Effect:** Potential minimal increase in revenues and expenditures due to the bill's penalty provisions.

**Small Business Effect:** Meaningful to the extent that any small business would receive a grant or loan from the fund.

## Analysis

**Bill Summary:**

*Maryland State Research Fund*

This special, nonlapsing fund, administered by TEDCO, consists of appropriations as provided for in the budget and any other money from any other source accepted for the fund's benefit. Investment earnings must be paid into the fund. Money from the fund may only be spent on: (1) grants and loans for State-funded stem cell research, in accordance with commission recommendations; (2) grants and loans for facilities, capital leases, and capital equipment where State-funded stem cell research is conducted, in accordance with commission recommendations; and (3) administration costs. Fund expenditures may only be made according to an appropriation approved by the General Assembly in the annual State budget or by an approved budget amendment.

"State-funded stem cell research" is research using donated unused material from infertility treatments or adult stem cells that are derived from human tissue and obtained after birth.

TEDCO, consulting with the commission, must adopt regulations to establish procedures for disbursing a grant contingent upon obtaining an institutional review board's approval. TEDCO may not disburse any grant until the institutional review board approves the grant's disbursal and the grantee and TEDCO enter into a memorandum of understanding that establishes the scope of the State's ownership or other financial interest in the commercialization and other benefits of the results, products, inventions, and discoveries of the research. The memorandum of understanding also must reflect that the institution's intellectual property policies, to the extent those policies are consistent with federal and State law.

Nothing in this bill can be construed to prohibit the creation of stem cell lines to be used for therapeutic research. State-funded research must be conducted ethically and the medical implications of the research must be considered. A person who conducts State-funded stem cell research may not engage in any research that intentionally and directly leads to human cloning.

Uncodified language requires TEDCO to review the stem cell research program and report to the Governor and the General Assembly on the feasibility and efficacy of maintaining the program if significant federal funding becomes available.

*Stem Cell Research Commission*

The commission must contract with an independent scientific peer review committee of scientifically recognized stem cell research experts. The peer review committee must review, evaluate, rank, and rate research proposals for State-funded stem cell research based on the commission's procedures and guidelines and in a manner that gives consideration to the scientific, medical, and ethical implications of the research. A committee member is not eligible to receive a grant or loan and may not live in Maryland. Committee members must be subject to conflict of interest standards that are at least as stringent as the conflict of interest standards adopted by the National Institutes of Health (NIH).

The commission must: (1) adopt regulations that ensure that fund-financed adult stem cell and stem cell research complies with State law; (2) develop criteria, standards, and requirements for the initial review of grant and loan applications; (3) review grant and loan applications based on criteria, standards, and requirements; (4) establish procedures and guidelines for the committee to review, evaluate, rank, and rate research proposals that are based on NIH Center for Scientific Review guidelines; (5) make recommendations regarding awarding grants and loans that are consistent with the standards and requirements established by the commission and based solely on the committee's rankings and ratings; (6) notify TEDCO regarding the submission by a grantee, or failure of a grantee, to submit institutional review board approval for a grant; (7) establish standards for the oversight and use of awards: (8) conduct progress oversight reviews of grantees; and (9) develop guidelines on disclosure and recusal to be followed by members of the commission when considering grant and loan applications.

The commission must meet at least twice annually, may employ its own staff, according to the State budget, and may consult with experts. TEDCO and the commission must report to the Governor and the General Assembly by January 1 of each year on the progress of State-funded stem cell research, including each grant funded, the funding amount, and a description of the research.

The Secretary of Business and Economic Development does not have the power to disapprove or modify any decision or determination the commission makes under authority specifically designated by law to the commission. The Secretary also does not have the power to transfer any of the commission's staff, functions, or funds.

*Disposition of Embryos and Eggs*

A licensed health care practitioner who treats an individual for infertility must provide the individual with sufficient information to enable an informed and voluntary choice

regarding the disposition of any unused material. The provider must present an individual the option of: (1) storing or discarding any unused material; (2) donating any unused material for clinical purposes in the treatment of infertility; (3) donating any unused material for research purposes; and (4) donating any unused material for adoption purposes. Any unused material donated for State-funded stem cell research may not be an oocyte. An individual who donates any unused material for research must give the health care provider written consent.

*Penalties*

A person may not purchase, sell, transfer, or obtain any donated unused material from infertility treatments for valuable consideration. A person may not give valuable consideration to another person to encourage the production of any donated unused material from infertility treatments for the sole purpose of medical research. A violator is guilty of a misdemeanor and on conviction is subject to a maximum penalty of three years imprisonment and/or a $50,000 fine.

A person may not conduct or attempt to conduct human cloning. A violator is guilty of a felony and on conviction is subject to a maximum penalty of 10 years imprisonment and/or a $200,000 fine.

**Current Law:** No law in Maryland specifically authorizes, bans, or otherwise regulates embryonic and fetal research. In the absence of State law, privately funded embryonic and fetal research can be conducted in Maryland without regulation.

**Background:**

*Governor's Fiscal 2007 Stem Cell Funding Initiative*

The fiscal 2007 budget includes $16.5 million to support stem cell research. The budget allocates $15 million for a new Stem Cell Research Fund to be administered by TEDCO. TEDCO helps create businesses and fosters their growth throughout the State by commercializing technology. Maryland research institutions and private companies conducting stem cell research would be eligible to apply for funding.

Additionally, the budget allocates $1.5 million for the Center for Regenerative Research at the University of Maryland, Baltimore's BioPark operating expenses.

*Other States' Stem Cell Funding Activities*

Several states are funding, or contemplating funding, stem cell research.

California's Proposition 71, passed at the November 2004 election, will provide $3 billion over the next 10 years for embryonic stem cell research. It establishes an Independent Citizens' Oversight Committee to oversee the new California Institute for Regenerative Medicine (CIRM). Two lawsuits challenging Proposition 71 are scheduled to go to court February 27, according to *amednews.com*. Meanwhile, CIRM is operating on a $3 million loan from the state and a $5 million private grant. The institute also is raising $50 million in private bonds to issue $39 million in research grants over three years. If a final court determination is that the state cannot fund stem cell research under Proposition 71, the private bonds will not be repaid, *amednews.com* reports.

New Jersey's fiscal 2006 budget appropriated $5.5 million for the Stem Cell Institute of New Jersey and $5 million to the Commission on Science and Technology to award Stem Cell Research Grants. On December 16, 2005, the commission awarded a total of $5 million in grants to 17 researchers at university, nonprofit, and corporate labs for stem cell research. Each grantee received up to $300,000 over two years. The state's fiscal 2005 budget appropriated $9.5 million for the Stem Cell Institute of New Jersey. The University of Medicine and Dentistry of New Jersey and Rutgers University each were provided $1 million, for a total of $11.5 million in fiscal 2005.

Connecticut enacted a bill in 2005 creating a fund to provide $10 million in grants per year over 10 years for adult and embryonic stem cell research. The bill appropriated $20 million to the fund for fiscal 2005. For each year beginning in fiscal 2008 and ending fiscal 2015, the bill requires a $10 million disbursement from the Tobacco Settlement Fund to the stem cell fund.

Illinois' governor issued an executive order in 2005 creating the Illinois Regenerative Medicine Institute that would award $10 million in grants to medical research facilities for stem cell research. Also in 2005, Massachusetts enacted a bill requiring the appointment of a commission to analyze and investigate the feasibility of establishing an Institute for Regenerative Medicine at the University of Massachusetts Medical School. The bill also permits research and clinical applications involving the derivation and use of human embryonic stem cells.

Virginia enacted a bill in 2005 establishing the Christopher Reeve Stem Cell Research Fund to be administered by the Commonwealth Health Research Board. The fund must be spent on stem cell research in state institutions of higher education relating to the causes and cures of diseases. The fund cannot support research using human embryonic

stem cells. Otherwise, the fund may support research not eligible for NIH research grants. This bill did not require a budget appropriation for the fund.

*Stem Cell Research*

There are two categories of stem cells: adult stem cells (e.g., those derived from specific human tissues such as skin cells); and embryonic stem cells. Embryonic research, including stem cell research, involves the destruction of a fertilized ovum. Embryonic stem cells currently hold the most promise for research but also are more controversial because of their source: fetal tissue; surplus embryos from in vitro fertility procedures; and embryos created by techniques utilized in human cloning technology – somatic cell nuclear transfer.

In August 2001, President Bush limited federal funding for embryonic stem cell research to existing embryonic stem cell lines. Such stem cells are derived from unused embryos from in vitro fertilization donated for research purposes. A Stem Cell Registry maintained by NIH lists the 78 stem cell lines that are eligible for federal funding. In addition, President Bush maintained the ban on federal funds for research involving the destruction or creation of embryos. However, such research can continue with the use of private funds, within the bounds of state law. The President's Council on Bioethics continues to study and advise the President on the issue of stem cell research.

In April 2005, the National Academies published Guidelines for Human Embryonic Stem Cell Research, which are a set of detailed suggestions for how institutions that conduct human embryonic stem cell research should regulate that research. The guidelines describe how institutions should proceed with human embryonic stem cell research and what types of research should be allowed under what circumstances.

Reports last year in the *Journal of Science* and the *New York Times* described Harvard Stem Cell Institute researchers' efforts to create embryonic stem cell lines without using or producing embryos. However, final research results are not yet available.

*Penalties*

Generally, with certain statutory exceptions, misdemeanor offenses are heard in the District Court and felony offenses are heard in the circuit courts. All jury trials are heard in the circuit courts.

**State Revenues:** General fund revenues could increase as a result of the bill's monetary penalty provisions from cases heard in the District Court. General fund revenues could potentially increase further as a result of the State financially benefiting from State-

funded research results. Due to the nature of this research and the complexity in applying any results into something that could reap financial gains, there would not be an increase in general fund revenues as a result of this research in the near future. When the State could see such revenues cannot be reliably determined at this time.

**State Expenditures:** No effect in fiscal 2007. General fund expenditures could increase significantly beginning in fiscal 2008 if the Governor includes an appropriation in the annual budget bill for the stem cell fund. The fiscal 2007 budget allocates $15 million for a new Stem Cell Research Fund to be administered by TEDCO, contingent on the passage of this bill or its cross file HB 1.

General fund expenditures could increase minimally as a result of the bill's incarceration penalties due to more people being committed to Division of Correction (DOC) facilities and increased payments to counties for reimbursement of inmate costs. The number of people convicted of this proposed crime is expected to be minimal.

Persons serving a sentence longer than 18 months are incarcerated in DOC facilities. Currently, the average total cost per inmate, including overhead, is estimated at $1,974 per month. This bill alone, however, should not create the need for additional beds, personnel, or facilities. Excluding overhead, the average cost of housing a new DOC inmate (including medical care and variable costs) is $341 per month. Excluding medical care, the average variable costs total $134 per month.

**Local Revenues:** Revenues could increase as a result of the bill's monetary penalty provisions from cases heard in the circuit courts.

**Local Expenditures:** Expenditures could potentially increase as a result of the bill's incarceration penalties. Counties pay the full cost of incarceration for people in their facilities for the first 90 days of the sentence, plus part of the per diem cost after 90 days. Per diem operating costs of local detention facilities are expected to range from $33 to $119 per inmate in fiscal 2006.

## Additional Information

**Prior Introductions:** A similar bill, HB 1183 of 2005, passed in the House and received a favorable report by the Senate Education, Health, and Environmental Affairs Committee but no further action was taken. Its cross file, SB 751, received a favorable report by the Senate Education, Health, and Environmental Affairs Committee but no further action was taken.

**Cross File:** HB 1 is listed as a cross file, but is not identical.

**Information Source(s):** Department of Health and Mental Hygiene; "Calif. suit on funding for stem cell research headed to court," amednews.com, January 16, 2006; "Assembly drops stem-cell legislation," *Philadelphia Inquirer*, January 4, 2006*; State Embryonic and Fetal Research Laws*, National Conference of State Legislatures; New Jersey Commission on Science and Technology; Department of Legislative Services

**Fiscal Note History:** First Reader - January 24, 2006
mll/jr Revised - Senate Third Reader - March 20, 2006
Revised - Updated Budget Information - May 15, 2006

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Analysis by: Lisa A. Daigle

Direct Inquiries to:
(410) 946-5510
(301) 970-5510