

Department of Legislative Services
Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE

Revised

House Bill 1183

(Delegate Rosenberg, *et al.*)

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

Maryland Cigarette Restitution Fund Spending and Stem Cell Research Act of 2005

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 2007, the Governor must include in the budget bill a \$23 million appropriation from the Cigarette Restitution Fund (CRF) to the stem cell fund and a \$2 million appropriation from CRF to prostate cancer screening and treatment programs. Additionally, the bill creates a Stem Cell Research Commission and a Maryland Scientific Peer Review Committee. 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.

Fiscal Summary

State Effect: Potential increase in general fund revenues and expenditures due to the bill's penalty provisions beginning in FY 2006. Potential significant increase in general fund revenues in future years to reflect the State's financial interest in State-funded stem cell research. Beginning in FY 2007, special fund expenditures would increase by \$25 million. Future years reflect a stable amount of special fund expenditures. Potential increase in special fund revenues beginning in FY 2007 due to any interest earned on stem cell fund deposits and any other money deposited into the stem cell fund.

(\$ in millions)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
GF Revenue	-	-	-	-	-
SF Revenue	0	-	-	-	-
GF Expenditure	-	-	-	-	-
SF Expenditure	0	25.0	25.0	25.0	25.0
Net Effect	\$0	(\$25.0)	(\$25.0)	(\$25.0)	(\$25.0)

Note: () = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: Potential significant 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 Stem Cell Research Fund

This special, nonlapsing fund, administered by the Department of Health and Mental Hygiene (DHMH), consists of CRF appropriations 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; (2) grants and loans for facilities, capital leases, and capital equipment where State-funded stem cell research is conducted; 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. The Governor must make an appropriation from the fund that is consistent with the commission's recommendations for each fiscal year for which appropriations are made for State-funded stem cell research.

The Secretary of Health and Mental Hygiene, consulting with the commission, must adopt regulations regarding fund expenditures, including: (1) criteria, standards, and requirements for funding applications and awarding grants and loans; (2) procedures for making disbursement of a grant contingent upon obtaining approval of an institutional review board and entering into a memorandum of understanding with DHMH; and (3) the standards for overseeing how the grants and loans are used. DHMH may not disburse any grant until the required approval is obtained and the required memorandum of understanding between the grantee and DHMH has been entered into. The memorandum of understanding between the grantee and DHMH will establish 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 State-funded stem cell research. It also will reflect the institution's intellectual property policies to the extent the policies are consistent with federal and State law.

Cigarette Restitution Fund

The bill adds the Stem Cell Research Fund as one of the purposes for which the CRF must be used. An appropriation from the CRF to the stem cell fund may not supplant any other appropriation required under the CRF or made to a program prior to fiscal 2007.

Maryland Scientific Peer Review Committee

The committee must: (1) establish procedures for reviewing research proposals for State-funded stem cell research; (2) ensure that the established procedures are based on National Institutes of Health's (NIH) Center for Scientific Review guidelines; (3) develop and implement a ranking and rating system to assess research proposals; and (4) make recommendations to the commission, based on rankings and ratings awarded to research proposals for awarding and disbursing grants. The committee must meet at least twice annually and must be staffed by DHMH.

Each committee member must disclose to the State Ethics Commission whether the member is employed by or has a financial interest in any entity that may apply to conduct State-funded stem cell research. All the committee's actions must occur at an open meeting.

Stem Cell Research Commission

The commission must: (1) ensure that fund-financed stem cell research complies with State law; (2) adopt regulations specifying how the commission will implement the bill's provisions; (3) recommend to the Secretary criteria, standards, and requirements for considering funding applications based on committee rankings, ratings, and standards for overseeing the use of awards; (4) review grant and loan applications based on criteria and standards; (5) make recommendations regarding awarding grants and loans that are consistent with the criteria and standards and based solely on the committee's rankings and ratings; (6) notify the Secretary regarding the submission by a grantee, or failure of a grantee, to submit institutional review board approval for a grant; and (7) conduct progress oversight reviews of grantees. The commission must meet at least twice annually and will be staffed by DHMH.

Each commission member must disclose to the State Ethics Commission whether the member is employed by or has a financial interest in any entity that may apply to conduct State-funded stem cell research. All the committee's actions must occur at an open meeting.

By January 1 each year, DHMH and the commission must report to the Governor and the General Assembly on the progress of State-funded stem cell research.

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 human embryos or oocytes. The provider must present an individual the option of: (1) storing or discarding unused human embryos or oocytes; (2) donating unused human embryos or oocytes for clinical purposes in the treatment of infertility; (3) donating unused human embryos or oocytes for research purposes; and (4) any other means of donation. An individual who donates unused human embryos or oocytes for research must give the health care provider written consent.

Penalties

A person may not purchase, sell, transfer, or obtain human embryos or oocytes for valuable consideration. A person may not give valuable consideration to any person to encourage the person to produce embryos or oocytes for the sole purpose of medical research. A violator is guilty of a misdemeanor and on conviction is subject to a maximum three-year prison term, a \$50,000 fine, or both.

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 10-year prison term, \$200,000 fine, or both.

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.

The CRF is a special, nonlapsing fund supported by revenue from a settlement with the five major tobacco companies. The CRF must be used to fund: the Tobacco Use Prevention and Cessation Program; the Cancer Prevention, Education, Screening, and Treatment Program; and other programs that serve health-related purposes as specified in statute. For each fiscal year for which CRF appropriations are made, at least 50% of the appropriations must be made for these programs. The State will pay the last of five installments to the Law Offices of Peter G. Angelos, P.C. in fiscal 2006, making an additional \$30 million available to the CRF in fiscal 2007. Beginning in fiscal 2008, Maryland could receive about \$28 million annually in strategic contribution payments, which reflects the State's legal contributions to the tobacco settlement.

Background: 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. New Jersey'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 provided \$1 million, for a total of \$11.5 million.

Wisconsin Governor Jim Doyle has outlined a multi-faceted strategy for biotechnology, health sciences, and stem cell research requiring \$750 million in expenditures over the next several years. Several components referencing stem cell research include: (1) a Wisconsin Institute for Discovery at the University of Wisconsin built and financed with state and private funds totaling \$375 million; and (2) \$105 million from the public sale of Blue Cross Blue Shield of Wisconsin to be used by the University of Wisconsin (\$75 million) and the Medical College of Wisconsin (\$30 million) to support public health, medical education, and research, including stem cell research.

New York Senate Democratic Leader David A. Patterson announced a \$1 billion stem-cell initiative that would require voter approval. Financing would come from the sale of up to \$1 billion in general obligation bonds, backed by the state's general fund, over a 10-year period. These funds would be used to create a New York Stem Cell Institute to award grants and loans to stem cell research companies and organizations. To put this initiative on the state's November 2005 or 2006 ballot, legislation must first be enacted.

Stem Cell Research

Embryonic research, including stem cell research, involves the destruction of a fertilized ovum. 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 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 (the council) continues to study and advise the President on the issue of stem cell research.

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 significantly reflecting the State's financial interest in the results, products, inventions, and discoveries of the State-funded stem cell research. The amount of revenues will depend on the terms of the memorandum of understanding between DHMH and the grantees.

State Expenditures: Special fund expenditures would increase by \$25 million in fiscal 2007, which accounts for the bill's October 1, 2005 effective date. This estimate reflects the cost of grants and loans for the purposes of stem cell research, funding of prostate cancer screening and treatment programs, and DHMH hiring four people (a physician, two program administrators, and a secretary) to staff the committee and commission, facilitate the review of funding applications and award grants and loans, conduct annual follow-up of research grants, and provide financial fund management. It includes salaries, fringe benefits, one-time start-up costs, travel expenses, and ongoing operating expenses.

Stem Cell Fund Grants and Loans	\$22,731,060
Prostate Cancer Screening and Treatment	2,000,000
Salaries and Fringe Benefits	247,213
Operating Expenses	<u>21,727</u>
Total FY 2007 State Expenditures	\$25,000,000

Future year expenditures reflect: (1) all special funds, minus \$2 million annually for prostate cancer screening and treatment programs, not used for operating expenses will be awarded as grants and loans; (2) full salaries with 4.6% annual increases and 3% employee turnover; and (3) 1% annual increases in ongoing operating expenses. This estimate does not reflect the additional expenditures of any interest the fund earns or other deposits that may be made into the fund. However, Legislative Services assumes the total amount of money in the fund will be completely spent by the end of each fiscal year.

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.

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 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: None.

Cross File: SB 751 (Senator Hollinger, *et al.*) – Education, Health, and Environmental Affairs and Budget and Taxation.

Information Source(s): Department of Health and Mental Hygiene; *State Human Cloning Laws*, National Conference of State Legislatures, October 7, 2003; *Human Cloning and Human Dignity: An Ethical Inquiry*, The President's Council on Bioethics, July 2002; Department of Legislative Services

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