HB 136

Department of Legislative Services

Maryland General Assembly
2006 Session

FISCAL AND POLICY NOTE

House Bill 136 (Delegate Shewell, *et al.*)
Health and Government Operations and Appropriations

Public Health - Adult and CBE Stem Cell Research Program

This bill creates the Adult and CBE Stem Cell Research Program within the Department of Health and Mental Hygiene (DHMH) to make grants and loans to qualified applicants conducting biomedical research using adult or cord-blood-derived-embryonic-like (CBE) stem cells. Beginning in fiscal 2008, the Governor must include in the State budget bill a $25 million appropriation from the Cigarette Restitution Fund (CRF) for the program. The appropriation may not supplant any other CRF-required appropriation or any CRF appropriation made to a program prior to fiscal 2008.

Fiscal Summary

State Effect: No effect in FY 2007. The projected CRF fund balance over the next five fiscal years is significantly lower than the $25 million appropriation required under the bill. As a result, due to the no supplantative provision of the bill, special fund expenditures could only increase by $3.3 million in FY 2008 to make biological research grants and loans and cover operational costs. This assumes the estimated CRF fund balance will not change. No effect on revenues. If the CRF fund balance is eliminated as a result of potential significant reductions in Master Settlement Agreement payments, little if any funding would be available to implement this bill.

($ in millions)	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Revenues	$0	$0	$0	$0	$0
SF Expenditure	0	3.3	4.8	3.2	2.2
Net Effect	$0	($3.3)	($4.8)	($3.2)	($2.2)

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

Local Effect: None.

Small Business Effect: Meaningful to the extent that any small business would receive a grant or loan under this program.

Analysis

Bill Summary: Any public or private group or organization, person, or individual from Maryland conducting biomedical research using adult or CBE stem cells may apply to DHMH for a grant or loan that must be applied to the cost of conducting the research. The grant or loan amount awarded must be determined on the merits of the application.

The Secretary of Health and Mental Hygiene must establish an institutional review board to which grant and loan applications must be directed. The review board must develop a science-based method of reviewing research projects submitted by applicants and use that method to review the applications. The review board must make a recommendation to the Secretary as to which applications should be approved and for DHMH to make funds available to approved applications. DHMH must approve any application on the review board's recommendation unless the application was not reviewed using the science-based method. The Secretary must adopt regulations for the disbursement of funds to the applicant. State funds allocated for this program may only be used for biomedical research using adult or CBE stem cells. No CRF funds may be provided to any person conducting research using stem cells from human embryos or aborted fetuses. The bill also prohibits human cloning.

The State may recover funds disbursed under this program from a recipient in the event of the recipient's failure to use the funds for biomedical research using adult or CBE stem cells. The State may recover an amount equal to the amount of State funds disbursed for the research project, together with all costs and reasonable attorneys' fees incurred by the State in the recovery proceedings. DHMH must adopt regulations to implement this program.

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.

Background:

Significant Reductions in CRF Funding Possible

Recent actions by several subsequent participating manufacturers threaten to reduce the amount of revenue available to the states. These manufacturers contend that manufacturers not participating in the Master Settlement Agreement have exploited legal loopholes to reduce their payments to the states, giving those manufacturers a competitive advantage in the pricing of their products. Approximately $84 million has been placed in escrow by the subsequent participating manufacturers pending resolution of the dispute by an arbitration. This amount, as well as $105 million overdue from the manufacturers, has reduced revenue immediately available to the State of Maryland by $4 million.

The possibility remains that additional companies, including the four original participating manufacturers, will withhold funds based on loss of market share. The Master Settlement Agreement authorizes manufacturers that lose a certain share of the market to withhold three times the amount of their losses. Based on preliminary estimates, an action of this sort has the potential to reduce payments under the Master Settlement Agreement by up to $1.1 billion or 18%, of which Maryland's share is approximately $26 million. The reduction would be applied to the fiscal 2006 payment due April 15, 2006. Industry leaders are in the process of reviewing past payments to determine the amount of losses.

It is difficult to anticipate at this time the magnitude or timing of challenges to payments under the Master Settlement Agreement. The nature of these disputes may vary based on state laws, the level of enforcement, and the amount of competition from nonparticipating manufacturers; likewise, the timeline and ultimate disposition of these cases will likely vary by jurisdiction.

Governor's Fiscal 2007 Stem Cell Funding Initiative

The fiscal 2007 proposed budget includes $33.5 million to support stem cell research. The budget allocates $20 million for a new Stem Cell Research Fund to be administered by the Maryland Technology Development Corporation (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 proposed budget allocates $12 million in capital funds for the Center for Regenerative Research at the University of Maryland, Baltimore's BioPark and $1.5 million to cover the center's first year of 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.

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 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 federal National Institutes of Health (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 to create embryonic stem cell lines without using or producing embryos. However, final research results are not available yet.

Umbilical Cord Blood Stem Cells

Umbilical cord blood is desirable for use in a stem cell transplant for the treatment of diseases, such as leukemia, because it has large numbers of blood stem cells. National Marrow Donor Program cord blood banks collect, process, test, and store donated umbilical cord blood. Blood from each umbilical cord is frozen and made available for transplant. If the blood cannot be used for transplant, the cord blood stem cells may be used for research. Public umbilical cord blood banks pay for the processing and storing costs of the donated blood.

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 Fiscal Effect: No effect on revenues or expenditures in fiscal 2007. Special fund expenditures could increase by an estimated $3,253,000 in fiscal 2008, which accounts for the bill's October 1, 2006 effective date and for the estimated CRF fund balance available for this bill's purposes. This estimate reflects the cost of grants and loans for the purposes of biomedical research and DHMH hiring three people (one physician, one program administrator, and one secretary) to staff the institutional review board, facilitate the review of funding applications and award grants and loans, conduct annual follow-up of research grants and loans, and provide financial fund management. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Stem Cell Fund Grants and Loans	$2,967,168
Salaries and Fringe Benefits	264,623
Operating Expenses	21,209
Total FY 2008 State Expenditures	**$3,253,000**

Future year expenditures reflect: (1) full salaries with 4.6% annual increases and 3% employee turnover; (2) 1% annual increases in ongoing operating expenses; (3) the variable estimated CRF fund balance; and (4) the bill's prohibition against diverting CRF funds from other programs. The bill does not provide for any unspent special funds to be carried over in the program's budget from fiscal 2008 to future fiscal years.

To the extent that Master Settlement Agreement payments to Maryland's CRF fund vary, the amount available to award grants and loans and pay for staffing and operational costs

also will vary. If the CRF fund balance is eliminated as a result of the potential significant reductions in Master Settlement Agreement payments, little if any funding would be available to implement this bill. Even without the potential loss of millions of dollars in CRF funds due to reduced Master Settlement Agreement payments, the estimated CRF fund balances are not enough to cover the costs of fully implementing this bill. Estimated CRF fund balances range from $2.5 million in fiscal 2007 to $4.8 million in fiscal 2009.

Estimated CRF Fund Balances

FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
$2.5 million	$3.3 million	$4.8 million	$3.2 million	$2.2 million

Source: Department of Budget and Management

Additional Information

Prior Introductions: A similar bill, HB 1356 of 2005, received an unfavorable report by the House Health and Government Operations Committee.

Cross File: None.

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; National Marrow Donor Program; Department of Legislative Services

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