

STEM CELL RESEARCH



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Stem Cell Research

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December 17, 2007

The Honorable Thomas V. Mike Miller, Jr., President of the Senate
The Honorable Michael E. Busch, Speaker of the House of Delegates
Members, Maryland General Assembly

Ladies and Gentlemen:

In recent years, there has been a growing national interest in stem cell research. This research has not been without controversy and has prompted significant legislative activity at both the federal and State level.

The Department of Legislative Services (DLS), in conjunction with faculty and students at the University of Maryland School of Law, first undertook a review of policy actions surrounding stem cell research in 2002. However, since that time, there have been potentially significant scientific breakthroughs with regard to the actual conduct of the research, much legislative activity, as well as a proliferation of State funding sources for this type of research. This report is intended to update that original DLS report.

This report was prepared by Marie Grant and Monica Kearns, reviewed by Simon Powell, with manuscript preparation by Kim Landry.

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Sincerely,

Karl S. Aro
Executive Director

Contents

Transmittal Letter	iii
Introduction.....	1
Overview of Stem Cell Research	1
The Difference between Adult Stem Cells and Embryonic Stem Cells	2
Sources for Embryonic Stem Cells.....	2
Stem Cell Research and the Federal Government.....	2
Federal Policy on Stem Cell Research Has Changed Little Since 2001.....	3
Federal Funding of Stem Cell Research Remains Level	3
Scientific Developments Point to Possible Resolution of Ethical and Moral Issues around Embryonic Stem Cell Research	3
Stem Cell Research and the States	4
State Policies toward Authorization of Stem Cell Research and Cloning Vary Widely .	4
Recent State Actions Concerning Stem Cell Research.....	4
State Funding of Stem Cell Research.....	5
To Date, Maryland’s Appropriations for Stem Cell Research Total \$38 Billion	5
Final 2007 Awards Being Negotiated; Deadline for 2008 Applications Is in January 2008	5
Proposals Are Considered from Experienced Investigators and Those New to the Field	6
Maryland Is Among Eight States That Have Funded Stem Cell Research.....	6
Conclusion	9
Appendix 1 Additional Sources.....	10

Stem Cell Research

Introduction

State funding of stem cell research and particularly embryonic stem cell research has been a topic of great debate in state legislatures across the country since President George Bush announced that federal funding of embryonic stem cell research could only be granted for research using embryonic stem cell lines that existed as of 2001. State responses to embryonic stem cell research have ranged from banning certain types of embryonic stem cell research to giving millions of dollars to support embryonic stem cell research.

This paper is divided into four parts:

- a brief overview of stem cell research and the controversy surrounding embryonic stem cell research;
- the status of federal policy regarding stem cell research and federal funding of stem cell research;
- an overview of state laws regarding stem cell research including the most recent developments at the state level; and
- an update on Maryland's State funded stem cell research as well as stem cell research funding in other states.

Overview of Stem Cell Research

The Difference Between Adult Stem Cells and Embryonic Stem Cells

Stem cells are unique and essential cells found in humans and animals. Many kinds of stem cells are found in the human body, with some more differentiated – or committed – to a particular function than others. When stem cells divide, some of the progeny mature into cells of a specific type (*e.g.*, heart, muscle, blood, or brain cells), while others remain stem cells. These stem cells are capable of continually reproducing themselves and serve to renew tissue throughout an individual's life. For example, they continually revitalize skin and produce a whole range of blood cells. Adult stem cells tend to be more differentiated, or committed, to a particular function or producing a particular type of cell. However, embryonic stem cells are pluripotent, or retain the ability to develop into nearly any cell type.

Sources for Embryonic Stem Cells

Embryonic stem cells are derived from the inner cell mass of a blastocyst *i.e.*, an early stage embryo, four to five days after fertilization. Embryonic stem cells can be derived from four primary sources: (1) existing stem cell lines; (2) aborted or miscarried embryos; (3) embryos that remain unused from in vitro fertilization; or (4) somatic cell nuclear transfer. Somatic cell nuclear transfer is a process through which an embryo is created by transferring a cell nucleus from a somatic cell (any cell other than an egg or sperm cell) into an oocyte, or egg cell, whose nucleus has been removed.

Somatic cell nuclear transfer is commonly referred to as cloning. If the cloning is used for production of a human embryo only for the purposes of extracting its stem cells, it is commonly referred to as “therapeutic cloning.” If the cloning is used to initiate a pregnancy, with the goal of producing a child who will be genetically virtually identical to an existing individual, it is referred to as “reproductive cloning.”

Stem Cell Research and the Federal Government

Federal Policy on Stem Cell Research Has Changed Little Since 2001

Since 1995, Congress had attached language to appropriations bills that prohibited the use of any federal funds for research that destroys or seriously endangers human embryos, or creates embryos for research purposes. This language is often referred to as the “Dickey Amendment,” for the amendment’s original author, former Representative Jay Dickey of Arkansas.

In 1999, the General Counsel of the U.S. Department of Health and Human Services wrote an opinion that funding of embryonic stem cell research might still be allowed under the amendment if the destruction of the embryos were funded by private sources. In August 2001, the Bush Administration adopted guidelines that limited federal funding for human embryonic stem cell research to the embryonic stem cell lines that had been derived at the time of the announcement of the guidelines. Additionally, the guidelines deny federal funding for the creation of human embryos for research purposes and for the cloning of human embryos for any purpose. (For a thorough summary of the history of federal policy regarding stem cell research, see *Monitoring Stem Cell Research*, by the President’s Council on Bioethics).

Since 2001, there have been several congressional attempts to pass federal legislation that authorizes additional funding for human embryonic stem cell research. The most recent of these was in early 2007, when the Stem Cell Research Enhancement Act of 2007 (S. 5) passed the U.S. Senate and the House of Representatives. However, the bill was vetoed by President Bush on June 20, 2007. The bill would have required the Secretary of Health and Human Services to conduct and support certain types of research utilizing human embryonic stem cells. The

research would have been limited to embryonic stem cells that were derived from human embryos donated from in vitro fertilization clinics for the purpose of fertility treatment and were in excess of the needs of the individuals seeking the treatment; would have otherwise been discarded; and obtained from individuals who donated the embryos with written informed consent and received no financial or other inducements.

With the veto of the Act in June, President Bush also issued an executive order that requires the Secretary of Health and Human Services to issue a plan that allows funding for research for pluripotent stem cells so long as they are derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm an embryo. This executive order may allow for federal funding for research that creates embryonic stem cells from embryos without destroying the embryos.

However, the *Washington Post* reported in July that some scientists are not sure whether the order will result in the funding of new embryonic stem cell lines, as the National Institute of Health (NIH) has not yet reported how the agency will decide which cell lines involve risks to embryos small enough to be eligible for funding.

Federal Funding of Stem Cell Research Remains Level

According to a brief by the Rockefeller Institute, federal funding from NIH for all kinds of stem cell research has remained relatively flat for the past four fiscal years and has amounted to about \$640 million annually. The estimated allocation for federal funding for fiscal 2008 is \$37 million for human embryonic stem cell research, \$205 million for human nonembryonic stem cell research, \$109 million for nonhuman embryonic stem cell research, and \$287 million for nonhuman nonembryonic stem cell research.

Scientific Developments Point to Possible Resolution of Ethical and Moral Issues Around Embryonic Stem Cell Research

As government at both the federal and, as detailed below, state level continues to grapple with the ethical issues surrounding embryonic stem cell research, several recent scientific studies have suggested that new embryos may not need to produce stem cells that have pluripotent properties, or even embryonic stem cells:

- In October 2005, the *New York Times* reported on Harvard researchers who are conducting research based on the premise of using an egg to create embryonic stem cell lines but in a way that embryos are not produced. The process would use an adult cell and an egg and would remove or alter genes from the adult cell so that an embryo would not be produced. That altered cell would then be added to the egg to generate embryonic stem cell lines.

- A study published in the January 2007 edition of the journal *Nature Biotechnology* found that stem cells derived from human amniotic fluid appear to offer many of the benefits of embryonic stem cells.
- In November 2007, the *Washington Post* reported that two research teams, one in Wisconsin and one in Japan, turned human skin cells into cells that behave like embryonic stem cells without using embryos or eggs. The research teams accomplished the feat by using genetically engineered viruses to change adult cells into cells that have embryo-like properties. Shinya Yamanaka of Kyoto University dubbed these cells “induced pluripotent stem cells,” as they are not exactly the same as embryonic stem cells. Though the breakthrough cannot be immediately used for medical treatment, as the viruses used to trigger the change in the cells may cause tumors, scientists believe that the technique can immediately be used for research purposes.

Stem Cell Research and the States

State Policies Toward Authorization of Stem Cell Research and Cloning Vary Widely

States have adopted varying policies toward human embryonic stem cell research and cloning. According to the National Conference of State Legislatures, 15 states, including Maryland, prohibit reproductive cloning: Arkansas, California, Connecticut, Illinois, Indiana, Iowa, Maryland, Massachusetts, Michigan, Missouri, Rhode Island, New Jersey, North Dakota, South Dakota, and Virginia. Five of these states – Arkansas, Indiana, Michigan, North Dakota, and South Dakota – also prohibit therapeutic cloning. Arizona prohibits the use of public monies for reproductive or therapeutic cloning. Louisiana prohibits any kind of research on embryos created through in vitro fertilization or on fetuses or embryos in utero.

Recent State Actions Concerning Stem Cell Research

Recent state legislative actions regarding embryonic stem cell research policy include:

- **Illinois:** In August 2007, the Governor of Illinois signed into law Senate Bill 4, a measure that prohibits reproductive cloning but specifically authorizes several kinds of stem cell research, including therapeutic cloning. The law also establishes an oversight committee of seven members to oversee the Illinois Regenerative Medicine Institute’s grant decisions. (This institute had been previously established by executive order.) The law allows cloning to create cells for research purposes. The law also establishes procedures for couples to donate unused embryos created for in vitro fertilization to research.

- **Iowa:** In March 2007, the Governor of Iowa signed into law Senate File 162, a bill that repealed the state's five-year-old ban on somatic cell nuclear transfer, or therapeutic cloning. Iowa law continues to prohibit reproductive cloning.
- **Missouri:** In November 2006, Missouri voters approved a constitutional amendment that protects human embryonic stem cell research, including therapeutic cloning, but bans human reproductive cloning. However, according to an August 2007 article in the *New York Times*, the future of the amendment remains uncertain, with many in the Missouri General Assembly strongly opposed to the amendment's authorization of therapeutic cloning. In August 2007, a group filed a ballot proposal with the Missouri Secretary of State for the November 2008 election that would prohibit somatic cell nuclear transfer by redefining cloning.
- **New Jersey:** In July 2007, the Governor of New Jersey signed a bill authorizing a referendum on November 6, 2007, asking voters to approve borrowing \$450 million over 10 years for stem cell research. The funding would be used to award grants to institutions for research on adult stem cell research, embryonic stem cell research, and umbilical cord blood. The referendum was defeated by a 53 to 47 percent margin.

State Funding of Stem Cell Research

To Date, Maryland's Appropriations for Stem Cell Research Total \$38 Million

Maryland's support for stem cell research began with a \$15 million appropriation for fiscal 2007, followed by a \$23 million appropriation for fiscal 2008. Maryland research institutions and private companies may apply for these grant funds from the Maryland Stem Cell Research Fund, which was established by Chapter 19 of 2006, for human embryonic and other stem cell projects.

Final 2007 Awards Being Negotiated; Deadline for 2008 Applications Is in January 2008

At this point, 24 recipients for the fiscal 2007 funds have been identified, but final award amounts are still being negotiated to take into account other funding sources secured for proposed projects and to verify that recipients can follow required procedures. Until these negotiations are complete, details on the fiscal 2007 projects will not be released, including whether they involve human embryonic stem cells. A request for applications for the fiscal 2008 funds was issued on October 1, 2007, and the deadline for application is January 15, 2008 (letters of intent were required by November 30, 2007).

The stem cell fund is administered by the Maryland Stem Cell Research Commission, which was established by the 2006 statute as an independent unit within the Maryland Technology Development Corporation. The commission establishes standards and requirements for State-supported stem cell research according to statutory provisions.

The research commission reviews the proposed research process for each project and makes final decisions about research awards. The commission includes 15 members, including the Attorney General or designee; patient advocates; individuals with experience in biotechnology; scientists who work for the University System of Maryland and The Johns Hopkins University and do not engage in stem cell research; bioethicists; and individuals with expertise in biomedical ethics as it relates to religion. Several commission members work at institutions that are applying for funding, and so the commission has adopted conflict of interest guidelines to help its members avoid inappropriately influencing commission decisions.

The research commission has formed a scientific peer review committee, which considers how proposed projects adhere to medical research standards. This committee reviews and ranks proposals under consideration by the research commission. Members of the peer review committee are not eligible to receive a grant or loan from the fund and may not reside in Maryland.

Proposals Are Considered from Experienced Investigators and Those New to the Field

As in fiscal 2007, the 2008 requests for applications call for projects involving basic as well as translational research with human stem cells of all types. Translational research means that there is relevance and potential use for clinical applications for patients.

One request for applications is designed for investigators with preliminary data supporting the research topic, and funding will be up to \$500,000 of direct costs per year for up to three years. The second request for applications is designed for investigators who are new to the stem cell field and are forming new approaches or models without any preliminary data – these may be funded up to \$100,000 of direct costs per year for up to two years.

Of the 24 award recipients identified for fiscal 2007, 7 are investigators with preliminary data, and 17 are investigators new to the field.

Maryland Is Among Eight States That Have Funded Stem Cell Research

Maryland is among at least eight states that have authorized funds for stem cell research, according to a Rockefeller Institute Policy Brief. As shown in **Exhibit 1**, other states authorizing funding for stem cell research are California, Connecticut, Illinois, Minnesota, New Jersey, New York, and Ohio.

Exhibit 1

State Support for Stem Cell Research

<u>State</u>	<u>Total Authorized (for Research and Capital)</u>	<u>Amounts Authorized by Year</u>	<u>Total Awarded to Date (for Research and Capital)</u>	<u>Amounts Awarded by Year</u>
CA	\$3 billion	\$18.7 million for fiscal 2006; \$182.2 million for fiscal 2007, including \$400,000 in private funds; \$832.0 million for fiscal 2008	\$208 million	\$208 million since fiscal 2006; breakdown by year not available
CT	\$100 million	\$20 million for fiscal 2006; \$80 million for fiscal 2008 to 2015 (\$10 million each year)	\$19.78 million	\$19.78 million awarded in November 2006
IL	\$15 million	\$10 million for fiscal 2006; \$5 million for fiscal 2007	\$15 million	\$10 million for fiscal 2006; \$5 million for fiscal 2007
MD	\$38 million	\$15 million for fiscal 2007; \$23 million for fiscal 2008	\$0	\$0; fiscal 2007 award recipients have been identified but final awards are still in negotiation
MN	\$15 million	\$15 million in capital funds from the University of Minnesota; breakdown by year not available	Information not available	Information not available
NJ	\$295.7 million	Research grants: \$5 million for fiscal 2006, \$10 million for fiscal 2007, \$10.7 million for fiscal 2008; Capital: \$270 million authorized in fiscal 2007	\$25.2 million	Research grants: \$5 million for fiscal 2006, \$10.2 million for fiscal 2007; Capital: \$10 million
NY	\$600 million	\$100 million in fiscal 2008; \$500 million for fiscal 2009 to 2018 (\$50 million per year)	\$0	\$0
OH	\$27.4 million	\$19.4 million in fiscal 2003; \$8 million in fiscal 2006	Information not available; funds were awarded to a public-private consortium	Information not available; funds were awarded to a public-private consortium

Source: California Institute for Regenerative Medicine, October 2, 2007 press release, www.cirm.ca.gov/; California Legislative Analysts' Office, telephone calls with analyst Steve Boilard, 916-445-4656, October 2007; Case Western Reserve University (Ohio), June 19, 2003 press release, <http://www.case.edu/pubs/cnews/2003/6-19/stemcell.htm>; May 16, 2006 press release, <http://blog.case.edu/case-news/2006/05/index>; Center for Stem Cell and Regenerative Medicine (Ohio), <http://ora.ra.cwru.edu/stemcellcenter/>; Connecticut Department of Public Health, <http://www.ct.gov/dph>; Connecticut Public Act 05-149 of 2005, www.cga.ct.gov; Fossett, James W. "Federalism by Necessity: State and Private Support for Human Embryonic Stem Cell Research." *Rockefeller Institute Policy Brief*, August 9, 2007; Illinois Regenerative Medicine Institute, April 24, 2006 and August 17, 2006 press releases, <http://www.idph.state.il.us/irmi/news.html>; Maryland State Budget, fiscal 2007 and 2008; Maryland Technology Development Corporation, www.marylandtedco.org; New Jersey Commission on Science and Technology, <http://www.state.nj.us/scitech/stemcell/>; New Jersey Commission on Science and Technology, telephone call with director Joshua Trojak, 609-984-1671, October 31, 2007; New Jersey Governor's Office, July 26, 2007 press release, <http://www.state.nj.us/governor/news/news/approved/20070725a.html>; New Jersey Legislature, Bill A2828/S1471 of the 2006-2007 session, <http://www.njleg.state.nj.us/>; New York Governor's Office, July 26, 2007 press release, http://www.ny.gov/governor/press/0726074_print.html; New York Senate Finance Committee, Staff Analysis of the SFY 2007-2008 Executive Budget, page 260, www.senate.state.ny.us/senatoreports; University of Minnesota Stem Cell Institute, <http://www.stemcell.umn.edu/stemcell/about/home.html>; University of Wisconsin, May 17, 2007 press release, <http://www.news.wisc.edu/packages/stemcells/>; Wisconsin Office of the Governor, April 25, 2006 executive order #147, http://www.wisgov.state.wi.us/search_media.asp?locid=19.

A number of points can be made from the exhibit:

- ***California Leads with \$3 Billion in Authorized Support.*** In California, voters approved Proposition 71 in 2004, which authorized \$3 billion in bond funding for stem cell research and facilities. Opponents of the measure mounted a legal challenge that halted bond issuances until recently, but funding mechanisms were devised so that a stem cell institute could be established and the grant-making process could begin. Opponents of Proposition 71 lost their legal challenge in May 2007 when the California Supreme Court declined to hear an appeal on the constitutionality of the measure, and the first \$250 million of the bonds was issued in October 2007.
- ***Other State Support Is Concentrated in the East and Midwest; Maryland Ranks Fifth in Total Authorized State Support.*** After California, support for stem cell research ranges from \$600 million in New York to \$15 million in Illinois and Minnesota. Maryland ranks fifth among eight states that have authorized state support.
- ***States Use Different Approaches to Support Stem Cell Research.*** For example, in Connecticut, \$20 million was authorized in fiscal 2006, and the \$80 million authorized from fiscal 2008 to 2015 will be disbursed from the state's tobacco settlement fund. In Illinois, the governor and comptroller created a state program in 2005 by executive order to fund stem cell research. In Minnesota, the University of Minnesota has used \$15 million of its state capital appropriations to support its stem cell institute.

New Jersey has authorized \$25.7 million for research grants and \$270.0 million for capital projects (several small stem cell related capital projects at two state universities have also received funds).

In Ohio, the state awarded \$19.4 million to a stem cell research consortium in fiscal 2003, including \$10.9 million in capital funds and \$8.6 million for nonembryonic stem cell research. Another \$8.0 million in research funds was awarded in fiscal 2006. The research support was from a technology transfer fund established with the state's tobacco settlement funds. The stem cell consortium includes Case Western Reserve University, Ohio State University, a university affiliated hospital and clinic, and a private biopharmaceutical company.

- ***Other Kinds of State Support.*** Wisconsin is not listed in Exhibit 1, but the University of Wisconsin is a major player in human embryonic stem cell research, and the institution supports an interdisciplinary group of faculty who work on these issues with administrative and support resources from various schools and departments. Although a specific amount of university support cannot be identified, and Wisconsin has no dedicated funds for stem cell research, the governor directed the Department of Commerce in April 2006 to invest at least \$5 million in recruiting and growing companies in the stem cell industry.

Conclusion

The federal government continues to level fund stem cell research and to not provide funding to embryonic stem cell research using embryonic stem cell lines created after 2001. As a result, states have taken a variety of positions on regulation and funding of stem cell research. Most states have remained silent on the issue, though 15 states have banned reproductive cloning and 5 states have banned both reproductive and therapeutic cloning. Ultimately, scientific studies and discoveries such as those finding pluripotent properties in non-embryonic stem cells, particularly the studies where scientists have turned skin stem cells into stem cells with pluripotent properties, may ease the ethical debate over stem cell research over time.

Eight states provide funding for stem cell research. Maryland ranks fifth among these eight states in the level of funding authorized for stem cell research, with a total of \$38 million since the effort was established by statute in 2006. At this point, recipients for the initial (fiscal 2007) funds have been identified, but final award amounts are still being negotiated to take into account other funding sources secured for proposed projects and to verify that recipients can follow required procedures.

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