SPONSOR: Sen. Venables & Sen. Blevins & Sen. Sorenson & Rep. Hudson & Rep. M Marshall ;
Sens. Sokola, Henry & Amick; Reps. Maier & Schooley

DELAWARE STATE SENATE
144th GENERAL ASSEMBLY

SENATE BILL NO. 5

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE BY ADOPTING THE DELAWARE REGENERATIVE MEDICINE ACT, PROHIBITING HUMAN REPRODUCTIVE CLONING, RECOGNIZING THE IMPORTANCE OF STEM CELL RESEARCH, INCLUDING ADULT, UMBILICAL CORD BLOOD, AMNIOTIC AND EMBRYONIC, AND ESTABLISHING A FRAMEWORK FOR THE ETHICAL CONDUCT OF EMBRYONIC STEM CELL RESEARCH.

WHEREAS, the 144th General Assembly considers it essential that the State of Delaware establish a responsible, ethical policy regarding the rapidly emerging science of regenerative medicine, human reproductive cloning and stem cell research conducted within the State of Delaware; and

WHEREAS, stem cell research is a key area of regenerative medicine that offers immense promise for developing new medical therapies and potential cures for such conditions as juvenile diabetes, diabetes, cancer, cardiovascular disease, Sickle Cell disease, Alzheimer's disease, Parkinson's disease, spinal cord injuries, birth defects, Osteoporosis, severe burn injuries, Multiple Sclerosis and HIV/AIDS; and

WHEREAS, stem cell research also offers a critical means to explore fundamental questions of biology and disease development; and

WHEREAS, stem cells may one day serve as test models for pharmaceutical development; and

WHEREAS, all reputable forms of stem cell research should be pursued, including adult, umbilical cord blood, amniotic and embryonic stem cells, because one is not a replacement for another and because new information resulting from one avenue of research may be key to advances in another area; and

WHEREAS, in recognition of the medical potential of adult stem cells and stem cells derived from umbilical cord blood, the State provided funding in the Fiscal Year 2007 grant-in-aid bill for a one-time appropriation to the Brady Kohn Foundation, a Delaware-based nonprofit organization, to help fund its community outreach initiative to educate members of the public on the lifesaving potential of umbilical cord blood; and

WHEREAS, stem cell research raises significant ethical and policy issues that must be carefully considered; and

WHEREAS, the establishment of an ethical policy that encourages the pursuit of state-of-the-art scientific research in the field of regenerative medicine, while guarding against its possible misuse, will help to ensure the long-term health and well being of Delawareans; and

WHEREAS, public policy on stem cell research must balance ethical and medical considerations, and said policy must be based on an understanding of the science associated with stem cell research and grounded on a thorough consideration of the ethical concerns regarding this research; and

WHEREAS, public policy on stem cell research must be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of stem cell research; and

WHEREAS, many prestigious scientific societies and leading research institutions in the United States, including, among others, the American Medical Association, the American College of Surgeons , the American Society for Cell Biology, the American Association for Cancer Research, the Society for Neuroscience, the Salk Institute for Biological Studies, Columbia University, Harvard University, Johns Hopkins University, the University of Pennsylvania, Yale University and Washington University in St. Louis, endorse stem cell research, including responsible and ethical embryonic stem cell research; and

WHEREAS, numerous societies and organizations dedicated to curing diseases that affect Delawareans and other Americans, such as the American Diabetes Association, the National Multiple Sclerosis Society, the Paralyzed Veterans of America, the Parkinson's Disease Foundation, and the Foundation Fighting Blindness, endorse stem cell research, including responsible and ethical embryonic stem cell research; and

WHEREAS, Delaware is home to such respected organizations as the University of Delaware, Delaware State University, the Nemours Foundation, the Alfred I. du Pont Hospital for Children, the Helen F. Graham Cancer Center, the Delaware Biotechnology Institute, and the Delaware Technology Park; and

WHEREAS, the State of Delaware, with its rich legacy of world leadership in scientific research and discovery, is actively promoting the development of biotechnology enterprises because of their potentially great importance to the health of our citizens as well as to the state's economy; and

WHEREAS, the 144th General Assembly is desirous of fostering research that will advance the state of medical and scientific knowledge, and will offer enormous potential to save human lives and treat heretofore incurable diseases, and which will also allow the State of Delaware to have a significant role in the emerging biomedical technology field, to the benefit of all of its citizens;

NOW THEREFORE:

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Title 16, Delaware Code, by inserting a new Chapter as follows:

"Chapter 30D. The Delaware Regenerative Medicine Act.

§ 3001D. Findings and purpose.

The 144th General Assembly considers it essential that the State of Delaware establish a responsible, ethical policy regarding the rapidly emerging science of regenerative medicine, human reproductive cloning and stem cell research conducted within the State of Delaware. Stem cell research is a key area of regenerative medicine that offers immense promise for developing new medical therapies and potential cures for many serious and previously incurable diseases and conditions. Moreover, it offers a critical means of exploring fundamental questions of biology and disease development.

The General Assembly believes that all reputable forms of stem cell research must be explored, including adult, umbilical cord blood, amniotic and embryonic, because knowledge gained from one form of stem cell research may be key to advances in another area. However, stem cell research raises significant ethical and policy issues that must be carefully considered. Not the least of these considerations is the misuse of these procedures for human reproductive cloning, which this Chapter prohibits, and the process of obtaining embryonic stem cells for research purposes, which practice this Chapter strictly limits. It also establishes severe penalties for violations of prescribed procedures to ensure that the process occurs in a moral and ethical manner.

Public policy on stem cell research must balance ethical and medical considerations. Such policy must be based on an understanding of the science associated with stem cell research and grounded on a thorough consideration of the ethical concerns regarding this research. Public policy on stem cell research must be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of stem cell research. It is the policy of the State of Delaware to foster research that will advance the state of medical and scientific knowledge, and will offer enormous potential to save human lives and treat heretofore incurable diseases, and which will also allow the State of Delaware to have a significant role in the emerging biomedical technology field, to the benefit of all of its citizens.

§ 3002D. Human reproductive cloning prohibition.

(a) As used in this section, the term 'human reproductive cloning' means implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus. This does not include somatic cell nuclear transplantation into eggs or embryonic stem cells for research or therapeutic purposes that do not involve implantation to initiate a pregnancy.

(b) A person who knowingly engages or assists, directly or indirectly, in the cloning of a human being is guilty of a Class E felony and shall be subject to a fine not to exceed $1,000,000.00 for each offense.

§ 3003D. Human embryonic stem cell research.

(a) Human embryonic stem cells shall be eligible for use in research in the State of Delaware if the cells meet each of the following:

(1) the stem cells were derived from human embryos that have been donated from In Vitro Fertilization clinics, were created for the purposes of fertility treatment, were in excess of the clinical need for individuals seeking such treatment, and are less than the developmental age of 14 days;

(2) prior to the consideration of the embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded;

(3) the individuals seeking fertility treatment donated the embryos with written informed consent and neither the individuals nor the clinic will receive any financial or other inducements to make the donation; and

(4) throughout the process, the individuals who created the embryos must be educated regarding their options with respect to any excess embryos, including embryo adoption, and may at any time up until the point of donation, change their minds.

(b) Any person, including any physician or fertility clinic who knowingly sells or attempts to sell an embryo is guilty of a Class E felony and shall be subject to a fine not to exceed $100,000.00 for each offense.

§ 3004D. Review of human embryonic stem cell research required.

(a) There is hereby established a Human Stem Cell Research Advisory Committee consisting of thirteen (13) members appointed by the Governor. Members of the initial Committee shall be appointed to staggered terms of one (1) to two (2) years, and thereafter all terms of appointment shall be four (4) years. The Committee shall consist of the following members:

(1) five (5) scientists, including at least two (2) from the private research sector with experience and training in biomedical and/or clinical research in the fields of cell differentiation, nuclear reprogramming, tissue formation and regeneration, cell biology, stem cell biology, developmental biology, regenerative medicine or related fields;

(2) two (2) medical ethicists;

(3) two (2) persons licensed to practice law with backgrounds in legal issues related to human embryonic stem cell research, in vitro fertilization, or family law, as it applies to the donation of blastocysts and oocytes;

(4) one (1) member of the Delaware disabilities community; and

(5) three (3) members of the public.

(b) Such staff assistance as may be required by the Committee for its operations shall be provided by the staff of the Delaware Health Care Commission.

(c) The Committee shall adopt guidelines for research involving the derivation or use of human embryonic stem cells in Delaware within six (6) months of enactment of this legislation. Such guidelines shall be consistent with established Federal guidelines, including (i) the guidelines for research using human pluripotent stem cells developed by the National Institutes of Health published in August 2000, and corrected in November 2000, and (ii) guidelines for research issued by the National Research Council and the Institute of Medicine of the National Academies, published in April, 2005. After adoption of the initial guidelines, the Committee may revise the guidelines or issue advisory opinions, as necessary, to account for developments in research and medicine as they may affect the research and ethical considerations associated with the use of human embryonic stem cells.

(d) Any such guidelines adopted or advisory opinions issued by the Committee shall only apply to research that is publicly funded by the State of Delaware.

(e) Whenever the Committee is asked to issue an advisory opinion as to whether proposed research meets Delaware's guidelines, the Committee may, at its direction, obtain the assistance of a Scientific Review Panel, at the expense of the party seeking the advisory opinion. The members of the Scientific Review Panel are to be recommended by the University of Delaware and are subject to the approval by the Committee. The Scientific Review Panel shall submit a written report to the Committee containing the Panel's findings and recommendations.

(f) The Committee shall issue an annual written report on its activities to the Governor, the Delaware General Assembly and the Director of the Delaware Division of Public Health on or before the first day of April of the year following any calendar year in which such activity has occurred.

(g) Any person, including any individual or legal entity of any kind who knowingly violates the guidelines adopted by the Committee shall be subject to a civil penalty not to exceed $500,000.00."

SYNOPSIS

This is the Delaware Regenerative Medicine Act. The purpose of this Act is to encourage and foster responsible, ethical and moral public policy governing research in the emerging science of regenerative medicine, which includes stem cell research of all types. Further, this Act seeks to ensure that any human embryonic stem cell research conducted in Delaware will adhere to broadly accepted standards. This Act prohibits and establishes penalties for the practice of, or the attempt to practice, human reproductive cloning. The Act also prohibits the sale of, or attempts to sell, human embryos in the State of Delaware.

The Act seeks to balance ethical concerns created by the use of human embryos less than two weeks old for medical and scientific research with the ethical obligations that exist to do everything possible to help seriously ill Delawareans whose health and well-being are endangered by debilitating, life-threatening illnesses and medical conditions. Stem cell research offers the potential to cure all genetically inherited diseases and many other conditions that are presently incurable, or for which limited treatment exists. These diseases and conditions include juvenile diabetes, diabetes, cancer, cardiovascular disease, Sickle Cell disease, Alzheimer's disease, Parkinson's disease, spinal cord injuries, birth defects, Osteoporosis, severe burn injuries, Multiple Sclerosis and HIV/AIDS. More than 130 million Americans are presently afflicted with these conditions.

At the present time, no mandatory standards are in place at either the federal or state level for research which is not federally-funded. However, a new set of voluntary "Guidelines for Human Embryonic Stem Cell Research" was issued on April 26, 2005, by a committee of the Board on Life Sciences of the National Research Council and the Health Sciences Policy Board of the Institute of Medicine (both affiliates of the National Academies) for the use of states and private industry. The Act would ensure that publicly-funded human embryonic stem cell research carried out in Delaware is conducted in accordance with such broadly accepted principles and procedures.

At present, excess human embryos created during In Vitro Fertilization procedures are typically discarded, and thus destroyed, when embryos are no longer needed for fertility treatment. This Act would permit couples whose cells created the embryos to donate them for legitimate medical and scientific research, if they so choose. A couple's decision to donate their excess embryos, instead of having them destroyed, would be strictly voluntary and would be made only

after they had been fully informed and educated regarding their options, including embryo adoption. The Act provides that as part of this "informed consent" process a couple would be free to change their minds at any time up to the point of donation.

This Act would permit scientific researchers to use donated human embryos less than the developmental age of 14 days, created during In Vitro Fertilization procedures for legitimate research projects, subject to restrictions. The restrictions would include the following: (a) a determination that the embryos would never be implanted in the female donor; (b) a requirement that the embryos would otherwise be discarded; (c) a requirement that the embryos are donated for the purpose of stem cell research by the individuals seeking fertility treatment; (d) a requirement that written informed consent would have to be obtained from the individuals donating the embryos; and (e) a prohibition that presents the individuals who are making the donation from receiving any financial or other inducements for the donation.

This Act would also establish a state "Human Stem Cell Research Advisory Committee" to develop and adopt guidelines for publicly-funded research involving the derivation or use of human embryonic stem cells. The Committee would be required to consider such applicable guidelines developed or used in the United States as those referred to above which have been developed by the National Academies. The Committee may revise the guidelines, or issue advisory opinions as necessary, to account for developments in research and medicine as they may affect the research and ethical considerations associated with the use of human embryonic stem cells.

When the Committee is asked to issue an advisory opinion it may, at its discretion, obtain the assistance of a Scientific Review Panel. The members of the Scientific Review Panel are to be drawn from a list recommended by the University of Delaware as possessing specialized expertise in the area under review, and are to be approved by the Committee. The Panel shall submit a written report of its findings and recommendations to the Committee.

The Committee shall issue an annual written report to the Governor, the Delaware General Assembly and the Director of the Delaware Division of Public Health for any year in which activity has occurred.

This Act is intended to foster new research in Delaware. Such research will help to advance medical treatment for Delaware citizens and maintain the State's leadership at the forefront of science and technology.

Author: Senator Venables

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