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 BILL ANALYSIS

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Senate Bills 647 and 648 (as introduced 6-18-09)
Sponsor: Senator Tom George (S.B. 647)
 Senator Mark C. Jansen (S.B. 648)
Committee: Health Policy

Date Completed: 10-27-09

CONTENT

Senate Bill 647 would amend the Public Health Code to do the following:

- Allow a person to conduct research that jeopardized the life or health of a donated human embryo that was created for fertility treatment but was not needed or suitable for implantation, if the research involved only the extraction or use of embryonic stem cells and other conditions were met.
- Require a person who conducted such research to file an annual report with the Department of Community Health (DCH).
- Require the DCH to compile an aggregate statistical report.
- Require the DCH to destroy an annual report from a researcher after five years.
- Limit the use of data from individual reports.
- Prescribe penalties for the disclosure of confidential identifying information and failure to file a required report.
- Prohibit a person from purchasing or selling a human embryo for stem cell research or therapies and cures.
- Prohibit a person from creating or attempting to create a human embryo for the purpose of conducting nontherapeutic research or a human-animal chimeric embryo, and designate a violation a felony.

Senate Bill 648 would amend the Code of Criminal Procedure to add to the

sentencing guidelines the creation of a human embryo for nontherapeutic research purposes or an animal chimeric embryo, and the disclosure of confidential identifying information by a person conducting research using live human embryos.

Senate Bill 648 is tie-barred to Senate Bill 647. The bills are described below in further detail.

Senate Bill 647

Human Embryo Research

The Public Health Code prohibits a person from using a live human embryo, fetus, or neonate for nontherapeutic research if, in the best judgment of the person conducting the research, based upon the available knowledge or information at the approximate time of the research, the research substantially jeopardizes the life or health of the embryo, fetus, or neonate. The bill would create an exception to this prohibition. Under the bill, pursuant to Article I, Section 27 of the State Constitution (described below, under **BACKGROUND**), a person could not conduct research that substantially jeopardized the life of health of a human embryo unless all of the following requirements were met:

- The research was permissible under Federal law and conducted pursuant to the requirements of Federal law.
- The embryo was created for fertility treatment purposes.

- The embryo was in excess of the clinical need of or was not suitable for implantation in the individual seeking the fertility treatment and would otherwise be discarded.
- The embryo was donated for research with the voluntary and written informed consent by the individual seeking the fertility treatment.
- The embryo had not been allowed to develop more than 14 days after cell division began, not including any time during which the embryo was frozen.
- The research involved only the extraction or use of embryonic stem cells from the embryo.

(Under the bill, "human embryo" would mean an organism consisting entirely of biological components of the species Homo sapiens capable of differentiation and maturation, regardless of the means of creation, including fertilization and somatic cell nuclear transfer, beginning from the single cell stage through the seventh week of development. "Created for fertility treatment purposes" would mean created for implantation and gestation in a woman's uterus by either in vitro fertilization (IVF), or the intentional division of a human embryo created by IVF. "Not suitable for implantation" would mean the human embryo exhibited physiological characteristics that, in the attending physician's best judgment, made successful implantation and gestation of the embryo less than 50% likely.

Under the Code, "nontherapeutic research" means scientific or laboratory research, or other kind of experimentation or investigation not designed to improve the health of the research subject.)

(A person who conducted research allowed under the bill would have to file an annual report with the DCH (described below).

Sale of Embryos

The bill would prohibit a person from purchasing or selling for valuable consideration a human embryo for stem cell research or therapies and cures as allowed under Article I, Section 27 of the State Constitution, or for any other purpose. ("Valuable consideration" would mean the payment or provision of anything of value, including cash, gifts, reduced fees for

services rendered, medical treatment, or payment for expenses or accommodations.)

Currently, the Code prohibits a person from knowingly selling, transferring, distributing, or giving away an embryo, fetus, or neonate for a use that violates Sections 2685 to 2689. The bill would eliminate the reference to selling, and would refer to donating instead of giving away.

(Sections 2685 to 2689 do the following:

- Prohibit a person from using a live human embryo, fetus, or neonate for nontherapeutic research if it substantially jeopardizes the life or health of the embryo, fetus, or neonate.
- Prohibit the performance of nontherapeutic research on an embryo or fetus known by the researcher to be the subject of a planned abortion performed for any purpose other than to protect the life of the mother.
- Provide that an embryo, fetus, or neonate is considered live if it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted embryo or fetus at approximately the same age of gestational development.
- Prohibit research from being performed knowingly upon a dead embryo, fetus, or neonate unless the mother's written consent has been obtained first.
- Require research performed upon a dead embryo, fetus, or neonate to be conducted in accordance with the standards applicable to research conducted under Part 101 (Revised Uniform Anatomical Gift Law) of the Code.
- Prohibit a person from performing or offering to perform an abortion if any of the consideration is that the embryo or fetus, whether alive or dead, may be used for research or study.)

A violation of the current prohibition is a felony punishable by up to five years' imprisonment. This penalty also would apply to a violation of the proposed prohibition.

Creation of Embryos; Penalties

The bill would prohibit a person from creating or attempting to create a human

embryo for the purpose of conducting nontherapeutic research upon it. In addition, the bill would prohibit a person from creating or attempting to create a human-animal chimeric embryo consisting of biological components from the species *Homo sapiens* and at least one other species where the embryo was capable of differentiating and maturing in a manner substantially similar to the embryonic maturation process of any of the species constituting the chimeric embryo. A person who violated these provisions would be guilty of a felony punishable by imprisonment for up to five years.

Annual Report; Penalties

Under the bill, a person who conducted permitted research using live human embryos annually would have to submit to the DCH a report on forms prescribed and provided by the Department and at the time and in the manner prescribed by the Department. A person who conducted research using living human embryos would have to collect and report only the following information to the DCH:

- The name of the company, corporation, academic institution, or other person managing or overseeing the research.
- The name and address of the physician's office or health facility or agency from where embryos were donated and the number of embryos acquired from each office or facility or agency.
- The number of embryos thawed for use in research.
- The number of embryos being discarded without being used for research.
- The number of embryos held in storage at the beginning and ending of the reporting year.

The DCH would have to do all of the following:

- Develop and make available in print and electronic format a form for people to use in filing the required report.
- Make available annually in aggregate a statistical report summarizing the information submitted in each individual report.
- Destroy each report and each copy of it after retaining the report for five years after it was received.

A person submitting a report could not include the name, common identifiers such as Social Security number or motor vehicle operator's license number, or other information or identifiers that would make it possible to identify in any manner or under any circumstances an individual who had obtained IVF services and who subsequently donated human embryos for research purposes. A State agency could not compare data in an electronic or other information system file with data in any other electronic or other information system that would result in identifying in any manner or under any circumstances an individual who donated human embryos for research. A person could not maintain statistical information that could reveal the identity of an individual who had donated human embryos for research.

The bill provides that the required reports would be statistical reports to be used only for medical and health purposes and could not be incorporated into the permanent official records of the system of vital statistics.

A person who disclosed confidential identifying information would be guilty of a felony punishable by imprisonment for up to one year and/or a maximum fine of \$5,000. A person who failed to file a required report would be responsible for a State civil infraction and could be ordered to pay a civil fine of at least \$5,000 per violation.

Senate Bill 648

Under the bill, the creation or attempted creation of a human embryo for nontherapeutic research purposes or the creation or attempted creation of an animal chimeric embryo would be a Class E felony against the public trust with a maximum penalty of five years' imprisonment. The disclosure of confidential identifying information by a person conducting research on live human embryos would be a Class G felony against the public trust, punishable by up to one year's imprisonment.

MCL 333.2685 et al. (S.B. 647)
777.13k (S.B. 648)

BACKGROUND

In 2008, Michigan voters adopted Proposal 08-2, which added Article I, Section 27 to

the State Constitution to address human embryo and embryonic stem cell research. Under Article I, Section 27, to ensure that Michigan citizens have access to stem cell therapies and cures, and to ensure that physicians and researchers can conduct the most promising forms of medical research in Michigan, and that all such research is conducted safely and ethically, any research permitted under Federal law is permitted in Michigan, subject to the requirements of Federal law and only the following additional limitations and requirements:

- No stem cells may be taken from a human embryo more than 14 days after cell division begins, excluding any time during which an embryo is frozen.
- The embryos were created for the purpose of fertility treatment and, with voluntary and informed consent, the person seeking fertility treatment chose to donate the embryos for research; and the embryos were in excess of the person's clinical need, or were not suitable for implantation, and would otherwise be discarded.
- No person may purchase or sell for valuable consideration human embryos for stem cell research or stem cell therapies and cures.

In addition, All stem cell research, therapies, and cures must be conducted and provided in accordance with State and local laws of general applicability, including laws concerning scientific and medical practices and patient safety and privacy, to the extent that any such laws do not prevent, restrict, obstruct, or discourage any permitted stem cell research, therapies, and cures; or create disincentives for anyone to engage in or otherwise associate with such research, therapies, or cures.

Article I, Section 27 provides that nothing in it alters Michigan's prohibition on human cloning.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bills would have an indeterminate fiscal impact on State and local government. There are no data to indicate how many offenders would be convicted of the proposed offenses. An offender convicted of the proposed Class E "create or attempt to

create human embryo or animal chimeric embryo" offense would receive a sentencing guidelines minimum sentence range of 0-3 months to 24-38 months, with a statutory maximum of five years. An offender convicted of the proposed Class G "person conducting research using live human embryos disclosing confidential information" offense would receive a sentencing guidelines minimum sentence range of 0-3 months to 7-12 months, with a statutory maximum of one year. Local governments would incur the costs of incarceration in local facilities, which vary by county. The State would incur the cost of felony probation at an annual average cost of \$2,000, as well as the cost of incarceration in a State facility at an average annual cost of \$32,000. Individuals convicted of either offense also could be subject to penal fines, not to exceed \$5,000. Any additional revenue collected under these classifications would benefit public libraries.

The Department of Community Health would see a marginal indeterminate increase in costs due to the requirement to collect and aggregate the reports on research using live human embryos.

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.