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FISCAL IMPACT REPORT

ORIGINAL DATE 01/22/09
 LAST UPDATED 01/26/09 **HB** _____

SPONSOR Ryan

SHORT TITLE Biomedical Research Act **SB** 77

ANALYST Hanika-Ortiz

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY09	FY10		
\$0.1 see narrative		Recurring	General Fund

(Parenthesis () Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From

- Department of Health (DOH)
- Health Policy Commission (HPC)
- Attorney General’s Office (AGO)
- Higher Education Department (HED)

SUMMARY

Synopsis of Bill

Senate Bill 77 expands the scope of prohibited activities addressed in the current Maternal, Fetal and Infant Experimentation Act; and, enacts the “Biomedical Research Act” permitting biomedical research on certain embryonic stem cells while at the same time attempting to prohibit human reproductive cloning. Punishment for violation of the new covered activities is a misdemeanor.

Sections 1 and 2: Cites the title of the new act as the “Biomedical Research Act”, and purpose which states the benefits of human embryonic stem cell research and other biomedical research.

Section 3: Defines terms used in the “Biomedical Research Act”, including:

- cell lines mean “a permanently established cell culture that will proliferate indefinitely...”;
- embryo is “an organism...up to eight weeks of age post-fertilization”;

- human reproductive cloning means “the asexual creation of an embryo”;
- in vitro “...also refers to a process or reaction occurring in an artificial environment”;
- pre-implementation embryo is “an embryo formed and maintained outside the body...that has not experienced more than fourteen days of development...”;
- primitive streak means “a structure that forms during the early stages of embryonic development...around the fourteenth day of existence”.

Section 4: Permits certain research and clinical applications involving the use of pre-implantation human embryonic stem cells targeted for disposal or deemed excess tissue. The research shall only be conducted with the informed consent of the original owner of the embryo and in accordance with guidelines promulgated by the United States Department of Health and Human Services Office for Human Research Protection, the National Research Council and the Institute of Medicine at the National Academies. The Act prohibits research involving in vitro culture of an intact human embryo for longer than 14 days or until formation of the primitive streak begins, whichever occurs first.

Section 5: Prohibits human reproductive cloning; includes purchasing, selling, transferring or obtaining human embryonic, gametic or cadaveric tissue for the purpose of reproductive cloning. Prohibits creating an embryo with the singular intent for research.

Section 6: Exempts an employee from the conduct of research, experimentation or study if it conflicts with their “sincerely held” religious practices or beliefs.

Section 7: Provides that violation of the Act is a misdemeanor and shall be punishable by a fine of up to \$25,000 or imprisonment for not more than 1 year or by both.

Section 8: Amends Section 24-9A-1 NMSA 1978, of the existing Maternal, Fetal and Infant Experimentation Act; within definitions, and **includes** in the definition of “clinical research” “products of conception produced by in vitro fertilization clinics and targeted for disposal or deemed excess tissue”. The bill **excludes** from the definition of fetus “products of conception produced by in vitro fertilization clinics and targeted for disposal or deemed excess tissue”.

FISCAL IMPLICATIONS

The bill creates guidelines for researchers studying human stem cells in New Mexico toward the goal of fostering such biomedical research within the state. The bill does not provide for nor authorize state funding for any research activities or clinical applications made possible by this bill.

These activities have the potential to require a future General Fund appropriation.

Proponents of the bill believe stem cell research over time has the potential to increase jobs, stimulate economic activity and improve health outcomes within the State.

SIGNIFICANT ISSUES

The AGO states that current New Mexico law appears to prohibit research activity on a “fetus”. This bill would permit limited stem cell research using embryos produced by in vitro fertilization clinics and targeted for disposal.

Scientists harvest embryonic stem cells from embryos left over in fertility clinics after in vitro fertilization procedures (IVF). When people undergo IVF, there are many more embryos created than can be implanted. Sometimes surplus embryos are discarded. Other times, they are donated to help other infertile couples, or for research.

PERFORMANCE IMPLICATIONS

The HPC reports that federally funded stem cell research must be conducted on stem cell lines derived from embryos that were created for reproductive purposes but no longer needed, and donated with the informed consent of the donors without any financial incentives.

ADMINISTRATIVE IMPLICATIONS

There is no state agency identified to provide oversight and regulatory authority for the activities this bill will generate.

TECHNICAL ISSUES

The Department of Health and Human Services publishes terms for Institutional Review Boards overseeing certain research activities and defines a “fetus” as the product of conception **from the time of implantation** until delivery. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development. The definition of “fetus” as used in the existing “Maternal, Fetal and Infant Experimentation Act” within New Mexico statute defines a “fetus” as the product of conception **from the time of** conception. The definition of “fetus” within existing New Mexico statute may need to be updated or clarified to avoid confusion.

OTHER SUBSTANTIVE ISSUES

The primitive streak (as defined above) is an important concept in bioethics, where some experts have argued that experimentation with human embryos is permissible only until the primitive streak develops, generally around the fourteenth day of existence. The development of the primitive streak is taken, by such bioethicists, to signify the creation of a unique, potential human being.

ALTERNATIVES

Create an advisory committee in an effort to provide useful advice to lawmakers by laying out the background on bio-ethical issues, analyzing the arguments, and presenting recommendations. In addition, the state could create a more permanent avenue to provide advice and expertise to lawmakers on other important ethical, legal, and policy issues that will arise from our increased understanding of human biology.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

HED reports that future opportunities for federally funded and approved stem cell research may conflict with existing state statute.

POSSIBLE QUESTIONS

What will “informed consent” of the original owner of the embryo include? Will the “original owner” only refer to the biological mother? Could a laboratory be ever considered an “original owner”?

AHO/svb