F I S C A L I M P A C T R E P O R T

SPONSOR Ryan **ORIGINAL DATE** 02/17/07 **LAST UPDATED** **HB**

SHORT TITLE EMBRYONIC STEM CELL BIOMEDICAL RESEARCH **SB** 894

ANALYST Hanika Ortiz

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY07	FY08	FY09	3 Year Total Cost	Recurring or Non-Rec	Fund Affected
Total		$.1 see narrative				

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION
LFC Files

Responses Received From
Department of Health (DOH)
Administrative Office of the Courts (AOC)

SUMMARY

Synopsis of Bill

Senate Bill 894 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 Act as the "Biomedical Research Act" and purpose of the Act which states the benefits of human embryonic stem cell and other biomedical research.

Section 3: Defines terms used in the Act, including:

- "embryo" is an organism of the species Homo sapiens formed by fertilization, somatic cell nuclear transfer, parthenogenesis or other means;
- "human adult stem cell" is an undifferentiated cell found in differentiated tissue that can renew itself and differentiate to yield specialized cell types;
- "human reproductive cloning" is the asexual genetic replication of a human being by transferring a pre-implantation embryo created by somatic cell nuclear transfer, parthenogenesis or by other asexual means into a uterus or uterine-like environment with the purpose of creating a human fetus or human child;

- "pre-implantation embryo" is an embryo formed and maintained outside the human body, whether by in vitro fertilization, somatic cell nuclear transfer, parthenogenesis or other asexual means that has not experienced more than fourteen days of development, not including time in suspension, such as through freezing.

Section 4: Permits certain research and clinical applications involving the use of pre-implantation human embryonic stem cells, including somatic cell nuclear transfer, human stem cells and umbilical cord stem cells. The research shall only be conducted in accordance with guidelines and policies promulgated by the National Research Council and the Institute of Medicine of 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 is first.

Section 5: Prohibits human reproductive cloning; attempted human reproductive cloning; purchasing, selling, transferring or obtaining human embryonic, gametic or cadaveric tissue for the purpose of reproductive cloning; and, creating an embryo with the sole intent of research. This subsection allows the creation of a pre-implantation embryo formed by asexual means for research purposes.

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, the Maternal, Fetal and Infant Experimentation Act; and, excludes from the definition of "fetus" products of conception produced by in vitro fertilization technology and targeted for disposal or deemed excess tissue.

FISCAL IMPLICATIONS

There is no appropriation or agency directed to establish policies and procedures needed to implement the Biomedical Research Act and amend the Maternal, Fetal and Infant Experimentation Act. This activity has the potential to require a general fund appropriation.

The National Institute of Health (NIH) is the Federal government's leading biomedical research organization. The NIH funds research scientists to conduct research on existing human embryonic stem cells and to explore the enormous promise of these unique cells, including their potential to produce breakthrough therapies and cures. Scientists are working with the NIH and the research community to establish a research infrastructure to ensure the successful handling and use of these cells in the laboratory. The bill creates guidelines for researchers studying human stem cells in New Mexico toward the goal of fostering such biomedical research within New Mexico.

SIGNIFICANT ISSUES

Stem cells formed in the earliest embryos are powerful because they can form any kind of cell. Scientists want to study them to find ways to better help the body repair itself. The use of human embryonic stem cells, which can be made either from embryos left over from fertility clinics or

by using cloning technology is controversial because of concerns about the sanctity of human life, and is restricted in some countries.

DOH notes that the public literature on stem cells considers "somatic cell nuclear transfer" (SCNT) and "parthenogenesis" synonymous with cloning activity.

Proposals to use SCNT techniques in human stem cell research raise a set of concerns beyond the moral status of any created embryo. One concern is that blastula creation in human stem cell research will lead to the reproductive cloning of humans (most researchers believe that in the foreseeable future it will not be possible to use this technique to produce a human clone that will develop to term). A second concern is the appropriate sourcing of the eggs that are needed. SCNT requires human eggs, which can only be obtained from women. The most common source of these eggs today are eggs that are produced and in excess of the clinical need during in vitro fertilization. This is a minimally invasive procedure, but it does carry some health risks.

Parthenogenesis is another form of asexual reproduction in which female eggs develop without fertilization by a male. The cells can be closely matched to the immune system of the recipient making them a potential source for transplants. In theory, the process could be used to reproduce humans but only after extensive testing and perfection.

The bill also amends the Maternal, Fetal and Infant Experimentation Act and excludes "products of conception produced by in vitro fertilization technology and targeted for disposal or deemed excess tissue" from the prohibitions on research; and, has the potential for serious ethical debate.

PERFORMANCE IMPLICATIONS

AOC comments that The National Conference of State Legislatures website, in discussing state embryonic and fetal research laws posted the following:

> "State laws may restrict the use of embryonic stem cells from some or all sources or specifically permit certain activities. State laws on the issue vary widely. Approaches to stem cell research policy range from statutes in California, Connecticut, Maryland, Massachusetts and New Jersey and an Executive Order in Illinois which encourage embryonic stem cell research; to South Dakota's law, which strictly forbids research on embryos regardless of the source. States that specifically permit embryonic stem cell research have established guidelines for scientists such as *consent requirements and approval and review processes for projects*."

ADMINISTRATIVE IMPLICATIONS

The bill is unclear which State agency is responsible to address ethical and legal issues including applicable federal laws; create standardized procedures to ensure that persons providing cells gave informed consent; and, establish criteria for the use of embryos and human eggs for research purposes and by whom.

TECHNICAL ISSUES

Section 3; defines "embryo" without a limitation upon the age of the organism. An embryo is considered to be from conception up to 8 weeks of age. Furthermore, DOH notes that the definition of fetus currently in the Maternal, Fetal and Infant Experimentation Act does not distinguish between embryonic and fetal stages (greater than 8 weeks).

Section 4(C); the bill does not contain a definition of "primitive streak". The bill restricts research involving an in vitro culture of an intact human embryo if older than fourteen days or until formation of the "primitive streak" begins, which ever occurs first. The primitive streak 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.

OTHER SUBSTANTIVE ISSUES

DOH comments that human stem cells are believed to hold promise for the understanding and treatment of many major acute and chronic developmental and degenerative diseases. Because of their potential to divide and specialize into many different cells types, stem cells have great potential for use in repairing damaged tissues to recover lost function. The ability of stem cells to be re-directed toward the development of different cells varies depending upon the source of the stem cell, with adult cells appearing to have more limited potential than embryonic, placental and amniotic stem cells.

ALTERNATIVES

Initiate a "New Mexico Advisory Committee on Human Cloning" in an effort to provide useful advice to lawmakers by laying out the background on the issues, analyzing the arguments, and presenting recommendations. In addition, the State should create a more permanent body to provide advice and expertise 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

Page 4, line 23 after the period insert "and the New Mexico department of health.

AHO/nt