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

SPONSOR Ryan **ORIGINAL DATE** 01-13-08 **LAST UPDATED** 01-30-08 **HB**

SHORT TITLE Biomedical Research Act **SB** 23/aSPAC/aSFl#1

ANALYST Hanika-Ortiz

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY08	**FY09**		
	$0.1 (see narrative)		General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From
Department of Health (DOH)

SUMMARY

Synopsis of SF#1 Amendment

The Senate Floor Amendment # 1 will allow research on embryos provided by consented donors after in vitro fertilization.

SIGNIFICANT ISSUE

For further clarity, the word "original" could be inserted before the word "owner" within the Amendment.

Synopsis of SPAC Amendment

The Senate Public Affairs Committee Amendment more accurately defines the term "embryo" to avoid confusion with the term "fetus"; clarifies and emphasizes the intent of the bill to limit stem cell research solely to embryos that are left over from in vitro fertilization clinics; and, emphasizes the intent of the bill that the creation of embryos by any means for the sole purpose of stem cell production is prohibited.

SIGNIFICANT ISSUES

DOH notes that SB23a does not change the intent or purpose of the original bill. SB 23a serves to clarify and emphasize key components in order to avoid any confusion in interpretation.

Synopsis of Original Bill

Senate Bill 23 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 Biomedical Research Act, including:

- cell lines mean "a permanently established cell culture that will proliferate indefinitely…";
- human adult stem cell is "an undifferentiated cell…that can renew itself and differentiate to yield specialized cell types";
- human reproductive cloning means "the asexual genetic replication of a human being by transferring a pre-implementation embryo…with the purpose of creating a human fetus…";
- pre-implementation embryo is "an embryo…that has not experienced more than fourteen days of development…";
- primitive streak means "the structure that forms during the early stages of embryonic development…and generally develops around the fourteenth day of existence".

Section 4: Permits certain research and clinical applications involving the use of pre-implantation human embryonic stem cells. The research shall only be conducted in accordance with guidelines and policies promulgated by the United States 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, and 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, the Maternal, Fetal and Infant Experimentation Act; within definitions, and 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. These activities have the potential to require a future General Fund appropriation.

However, there is no appropriation added to the bill or state agency identified to provide oversight and regulatory authority for the activities this bill will generate.

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 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.

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.

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.

PERFORMANCE IMPLICATIONS

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."*

TECHNICAL ISSUES

DOH has some concerns over the definitions provided for “embryo” and “fetus” as used in the Act. The Department insists that an “embryo” means the product of conception up to 8 weeks, while “fetus” means the product of conception from 8 weeks until expulsion.

DOH raises additional concerns that the bill may allow (by omission) the use of certain asexual as well as sexual techniques to produce embryos for stem cell production. Concerns surround somatic cell nuclear transplantation (SCNT) as embryos created by this technique have the same potential for development as do embryos created by fertilization.

SUBSTANTIVE ISSUES

Nearly a decade after the discovery of embryonic stem cells in humans, scientists still don't know exactly how they work, how to assure their purity, or what expected side effects they might have when transplanted into the human body.
However, scientists for the first time have made human embryonic stem cells without destroying embryos (a key issue), a development that the government's top stem cell official said may make the controversial research eligible for federal funding. However, there is a potential flaw with the technique as even the delicate removal of one cell could place an embryo's health at risk.

Researchers at Advanced Cell Technology in Worcester, Mass., created four stem cell lines out of individual cells plucked from 3-day-old embryos, which continued to appear to develop normally after the procedure.

The National Institute of Health's stem cell task force, said that with certain safeguards, the new method appeared to comply with federal restrictions that have largely cut scientists off from the **$28 billion** the government spends on medical research each year. Federal law prohibits the National Institutes of Health from paying for experiments that place human embryos at risk of injury or death, and spending on human embryonic stem cell research is restricted to projects involving a handful of cell lines that were created before August 2001.

The removal of a single cell from a young embryo is done thousands of times a year in the U.S. by fertility laboratories to screen embryos for genetic diseases. (January 11, 2008)
http://www.latimes.com/news/nationworld

ALTERNATIVES

Initiate 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 should 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.

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