SENATE JUDICIARY COMMITTEE SUBSTITUTE FOR SENATE BILL 1232

48TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2007

AN ACT

RELATING TO THE PUBLIC PEACE, HEALTH, SAFETY AND WELFARE;

PERMITTING BIOMEDICAL RESEARCH ON LIMITED CATEGORIES OF HUMAN

EMBRYONIC STEM CELLS; PROHIBITING HUMAN CLONING; AMENDING THE

MATERNAL, FETAL AND INFANT EXPERIMENTATION ACT.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

Section 1. [NEW MATERIAL] SHORT TITLE.--Sections 1 through 7 of this act may be cited as the "Biomedical Research Act".

Section 2. [NEW MATERIAL] FINDINGS AND PURPOSE. --

A. The legislature finds that an estimated one hundred twenty-eight million Americans suffer from the crippling physical, economic and psychological burdens of chronic, degenerative and acute diseases, including Alzheimer's disease, heart disease, diabetes, Parkinson's disease, spinal .168456.3

cord injuries, macular degeneration, multiple sclerosis, Lou Gehrig's disease and cancer. The legislature further finds that human embryonic stem cell research and other biomedical research in the life sciences and regenerative medicine present a significant chance of yielding fundamental biological knowledge from which may emanate therapies to relieve, on a large scale, human suffering from disease and injury.

B. The purpose of the Biomedical Research Act is to foster research and therapies in the life sciences and regenerative medicine by permitting research and clinical applications involving the derivation and use of certain human embryonic stem cells or stem cell lines while at the same time prohibiting human reproductive cloning.

Section 3. [NEW MATERIAL] DEFINITIONS.--As used in the Biomedical Research Act:

- A. "cell lines" means a permanently established cell culture that will proliferate indefinitely given appropriate fresh medium and space;
- B. "embryo" means an organism of the species Homo sapiens formed by fertilization;
- C. "fertilization" means the process whereby the male sperm and female ovum unite to form an embryo;
- D. "human adult stem cell" means an undifferentiated cell found in differentiated tissue that can renew itself and differentiate to yield specialized cell types; .168456.3

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- "human reproductive cloning" means the asexual Ε. genetic replication of a human being by transferring a pre-implantation embryo into a uterus or uterine-like environment with the purpose of creating a human fetus or a human child;
- "in vitro" means in an artificial environment, including a test tube or culture medium, and refers also to a process or reaction occurring in an artificial environment;
- "in vitro fertilization" means an assisted reproduction technique in which fertilization is accomplished outside the human body;
- "placental cells" means cells obtained from the Η. placenta;
- "pre-implantation embryo" means an embryo formed I. and maintained outside the human body, by in vitro fertilization, that has not experienced more than fourteen days of development; provided that such length of time does not include any interval in which the development has been suspended, such as through freezing;
- "primitive streak" means a structure that forms during the early stages of embryonic development and is characterized as a furrow in the midline of the embryonic disc, and generally develops around the fourteenth day of existence; and
- "umbilical cord stem cells" means cells derived .168456.3

from an umbilical cord.

Section 4.

LIMITATIONS--RESEARCH PROHIBITIONS.-
A. Research and clinical applications conducted in

[NEW MATERIAL] BIOMEDICAL RESEARCH PERMITTED--

- accordance with the Biomedical Research Act that involve the derivation and use of pre-implantation human embryonic stem cells derived from embryos produced by in vitro fertilization clinics and targeted for disposal or deemed excess tissue, stem cell lines, human adult stem cells from any source, umbilical cord stem cells and placental cells shall be permitted.
- B. Research involving the derivation of human embryonic stem cells through the use of human genetic material, as permitted by Subsection A of this section, shall only be conducted in accordance with guidelines and policies promulgated by the United States department of health and human services' office for human research protection as well as the national research council and the institute of medicine of the national academies.
- C. Research that involves in vitro culture of an intact human embryo, regardless of derivation method, for longer than fourteen days or until formation of the primitive streak begins, whichever occurs first, may not be conducted.
- Section 5. [NEW MATERIAL] HUMAN REPRODUCTIVE CLONING PROHIBITED.--
- A. It is unlawful knowingly to engage or assist in .168456.3

human reproductive cloning or attempted human reproductive cloning of a human being.

- B. A person shall not knowingly purchase, sell, transfer or otherwise obtain human embryonic, gametic or cadaveric tissue for the purpose of reproductive cloning.
- C. A person shall not knowingly create an embryo by the method of fertilization with the sole intent of donating the embryo for research.

Section 6. [NEW MATERIAL] SCIENTIFIC RESEARCH--EXEMPT EMPLOYEES.--An employee shall not be required to conduct scientific research, experimentation or study that involves the creation or use of pre-implantation embryos in relation to human embryonic stem cell research to the extent that such research conflicts with the sincerely held religious practices or beliefs of the employee.

Section 7. [NEW MATERIAL] PENALTIES.--Violation of the provisions of the Biomedical Research Act is a misdemeanor and shall be punishable by a fine of not more than twenty-five thousand dollars (\$25,000) or imprisonment for not more than one year or by both fine and imprisonment.

Section 8. Section 24-9A-1 NMSA 1978 (being Laws 1979, Chapter 132, Section 1, as amended) is amended to read:

"24-9A-1. DEFINITIONS.--As used in the Maternal, Fetal and Infant Experimentation Act:

A. "viability" means that stage of fetal .168456.3

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development when the unborn child is potentially able to live outside the mother's womb, albeit with artificial aid;

- B. "conception" means the fertilization of the ovum of a human female by the sperm of a human male;
 - C. "health" means physical or mental health;
- D. "clinical research" means any biomedical or behavioral research involving human subjects, including the unborn, conducted according to a formal procedure. The term is to be construed liberally to embrace research concerning all physiological processes in [man] human beings and includes research involving human in vitro fertilization, but shall not include diagnostic testing, treatment, therapy or related procedures conducted by formal protocols deemed necessary for the care of the particular patient upon whom such activity is performed and shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to [insure] ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a deformed or handicapped child; and provided that emergency medical procedures necessary to preserve the life or health of the mother or the fetus shall not be considered to be clinical research;
- E. "subject at risk", "subject" or "at risk" means .168456.3

any individual who may be exposed to the likelihood of injury, including physical or psychological injury, as a consequence of participation as a subject in:

- (1) any research, development or related activity [which] that departs from the application of those established and accepted methods deemed necessary to meet [his] the individual's needs;
- (2) controlled research studies necessary to establish accepted methods designed to meet [his] the individual's needs; or
- (3) research activity [which] that poses a significant risk to the subject;
- F. "significant risk" means any activity [which]

 that is likely to cause disfigurement or loss or impairment of
 the function of any member or organ;
- G. "fetus" means the product of conception from the time of conception until the expulsion or extraction of the fetus or the opening of the uterine cavity, but shall not include the placenta, extraembryonic membranes, umbilical cord, extraembryonic fluids and their resident cell types, [and] cultured cells or products of conception produced by in vitro fertilization clinics and targeted for disposal or deemed excess tissue;
- H. "live-born infant" means an offspring of a human being [which] that exhibits either heartbeat, spontaneous .168456.3

respiratory activity, spontaneous movement of voluntary muscles or pulsation of the umbilical cord if still attached to the infant ex utero; provided the Maternal, Fetal and Infant Experimentation Act does not apply to a fetus or infant absent the characteristics set forth in this subsection;

- I. "infant" means an offspring of a human being from the time it is born until the end of its first chronological year;
- J. "born" means the time the head or any other part of the body of the fetus emerges from the vagina or the time the uterine cavity is opened during a caesarean section or hysterotomy; and
- K. "in vitro fertilization" means any fertilization of human ova [which] that occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means."

Section 9. Section 24-9A-7 NMSA 1978 (being Laws 1979, Chapter 132, Section 7) is amended to read:

"24-9A-7. SHORT TITLE.--[Sections 1 through 7 of this act] Chapter 24, Article 9A NMSA 1978 may be cited as the "Maternal, Fetal and Infant Experimentation Act"."

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