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SENATE BILL 313

51ST LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2013

INTRODUCED BY

Bill B. O'Neill

AN ACT

RELATING TO HEALTH; PERMITTING BIOMEDICAL RESEARCH ON LIMITED CATEGORIES OF HUMAN EMBRYONIC STEM CELLS; REQUIRING OVERSIGHT; PROHIBITING HUMAN CLONING; IMPOSING PENALTIES; 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] DEFINITIONS.--As used in the Biomedical Research Act:

A. "cell lines" means a permanently established cell culture that will proliferate indefinitely given the appropriate laboratory conditions;

B. "embryo" means a fertilized human egg that has

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1 begun cell division;

2 C. "fertilization" means the process whereby the
3 male sperm and female ovum unite to form an embryo;

4 D. "human adult stem cell" means an
5 undifferentiated cell found in differentiated tissue that can
6 renew itself and differentiate to yield specialized cell types;

7 E. "human reproductive cloning" means the asexual
8 creation of an embryo;

9 F. "in vitro" means in a laboratory or clinical
10 environment, including a test tube or culture medium, and also
11 refers to a process or reaction occurring in a laboratory or
12 clinical environment;

13 G. "in vitro fertilization" means an assisted
14 reproduction technique in which fertilization is accomplished
15 outside the human body;

16 H. "placental cells" means cells obtained from the
17 placenta;

18 I. "pre-implantation embryo" means an embryo formed
19 and maintained outside the human body, by in vitro
20 fertilization, that has not experienced more than fourteen days
21 of development, excluding time the embryo was cryopreserved or
22 frozen;

23 J. "primitive streak" means a structure that forms
24 during the early stages of embryonic development and is
25 characterized as a furrow in the midline of the embryonic disc

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1 and generally develops around the fourteenth day of existence;
2 and

3 K. "umbilical cord stem cells" means cells derived
4 from an umbilical cord.

5 SECTION 3. [NEW MATERIAL] BIOMEDICAL RESEARCH PERMITTED--
6 LIMITATIONS--RESEARCH PROHIBITIONS.--

7 A. Research and clinical applications conducted in
8 accordance with the Biomedical Research Act that involve the
9 derivation and use of pre-implantation human embryonic stem
10 cells are permitted; provided that they are derived from:

11 (1) embryos that are produced by in vitro
12 fertilization clinics and designated for destruction;

13 (2) stem cell lines;

14 (3) human adult stem cells from any source;

15 (4) umbilical cord stem cells; and

16 (5) placental cells.

17 B. Research involving the derivation of human
18 embryonic stem cells, as permitted by Subsection A of this
19 section, shall only be conducted with the informed consent of
20 the original progenitors or recipients pursuant to a sperm or
21 egg donation agreement and in accordance with guidelines and
22 policies promulgated by an institutional review board as
23 provided in Section 4 of the Biomedical Research Act, which
24 shall take into account the recommendations of the United
25 States department of health and human services' office for

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1 human research protections, the national research council and
2 the institute of medicine of the national academies.

3 C. Research may be conducted on a human embryo,
4 regardless of derivation method, until formation of the
5 primitive streak begins.

6 SECTION 4. [NEW MATERIAL] INSTITUTIONAL REVIEW BOARD
7 OVERSIGHT REQUIRED.--A person or institution conducting stem
8 cell research shall submit its activities to the oversight of
9 an institutional review board. The institutional review board
10 shall:

11 A. provide oversight over all issues related to
12 derivation and use of stem cells;

13 B. review and approve the scientific merit of
14 research protocols;

15 C. review compliance of all stem cell research with
16 all relevant regulations and guidelines; and

17 D. perform such other activities as may be
18 necessary or appropriate and consistent with nationally
19 recognized institutional review board standards or protocols or
20 as may be provided by law.

21 SECTION 5. [NEW MATERIAL] HUMAN REPRODUCTIVE CLONING
22 PROHIBITED.--

23 A. It is unlawful to knowingly engage or assist in
24 human reproductive cloning or attempted human reproductive
25 cloning of a human being.

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1 B. A person shall not knowingly purchase, sell,
2 transfer or otherwise obtain human embryonic, gametic or
3 cadaveric tissue for the purpose of human reproductive cloning.

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

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

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

18 "24-9A-1. DEFINITIONS.--As used in the Maternal, Fetal
19 and Infant Experimentation Act:

20 A. "viability" means that stage of fetal
21 development when the unborn child is potentially able to live
22 outside the mother's womb, albeit with artificial aid;

23 B. "conception" means the fertilization of the egg
24 of a human female by the sperm of a human male;

25 C. "health" means physical or mental health;

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1 D. "clinical research" means any biomedical or
2 behavioral research involving human subjects, including
3 embryos, conducted according to a formal procedure. The term
4 is to be construed liberally to embrace research concerning all
5 physiological processes in human beings and includes research
6 involving human in vitro fertilization, but shall not include
7 diagnostic testing, treatment, therapy or related procedures
8 conducted by formal protocols deemed necessary for the care of
9 the particular patient upon whom such activity is performed and
10 shall not include human in vitro fertilization performed to
11 treat infertility;

12 E. "subject at risk", "subject" or "at risk" means
13 any person who may be exposed to the likelihood of injury,
14 including physical or psychological injury, as a consequence of
15 participation as a subject in:

16 (1) any research, development or related
17 activity that departs from the application of those established
18 and accepted methods deemed necessary to meet the person's
19 needs;

20 (2) controlled research studies necessary to
21 establish accepted methods designed to meet the person's needs;
22 or

23 (3) research activity that poses a significant
24 risk to the subject;

25 F. "significant risk" means an activity that is

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1 likely to cause disfigurement or loss or impairment of the
2 function of any member or organ;

3 G. "fetus" means the product of conception from the
4 [~~time of~~] end of the eighth week after conception until the
5 expulsion or extraction of the fetus or the opening of the
6 uterine cavity, but shall not include the placenta,
7 extraembryonic membranes, umbilical cord, extraembryonic fluids
8 and their resident cell types, [~~and~~] cultured cells or products
9 of conception produced by in vitro fertilization clinics and
10 designated for destruction;

11 H. "live-born infant" means an offspring of a
12 person that exhibits heartbeat, spontaneous respiratory
13 activity, spontaneous movement of voluntary muscles or
14 pulsation of the umbilical cord if still attached to the infant
15 ex utero; provided that the Maternal, Fetal and Infant
16 Experimentation Act does not apply to a fetus or infant absent
17 the characteristics set forth in this subsection;

18 I. "infant" means an offspring of a human being
19 from the time it is born until the end of its first
20 chronological year;

21 J. "born" means the time the head or any other part
22 of the body of the fetus emerges from the vagina or the time
23 the uterine cavity is opened during a caesarean section or
24 hysterotomy; and

25 K. "in vitro fertilization" means [~~any~~

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1 ~~fertilization of human ova that occurs outside the body of a~~
2 ~~female, either through admixture of donor human sperm and ova~~
3 ~~or by any other means]~~ an assisted reproduction technique in
4 which fertilization is accomplished outside the human body."

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

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

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