111TH CONGRESS
1ST SESSION

S. 487

To amend the Public Health Service Act to provide for human embryonic stem cell research.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 2009

Mr. HARKIN (for himself, Mr. SPECTER, Mr. KENNEDY, Mr. HATCH, Mrs. FEINSTEIN, and Mr. REID) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to provide for human embryonic stem cell research.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stem Cell Research Enhancement Act of 2009''.

SEC. 2. HUMAN EMBRYONIC STEM CELL RESEARCH.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 498C the following:

"SEC. 498D. HUMAN EMBRYONIC STEM CELL RESEARCH.

''(a) IN GENERAL.—Notwithstanding any other provision of law (including any regulation or guidance), the Secretary shall conduct and support research that utilizes human embryonic stem cells in accordance with this section (regardless of the date on which the stem cells were derived from a human embryo).

''(b) ETHICAL REQUIREMENTS.—Human embryonic stem cells shall be eligible for use in any research conducted or supported by the Secretary if the cells meet each of the following:

''(1) The stem cells were derived from human embryos that have been donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment.

''(2) Prior to the consideration of embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded.

''(3) The individuals seeking fertility treatment donated the embryos with written informed consent and without receiving any financial or other inducements to make the donation.

''(c) GUIDELINES.—Not later than 60 days after the date of the enactment of this section, the Secretary, in consultation with the Director of NIH, shall issue final guidelines to carry out this section.

''(d) REPORTING REQUIREMENTS.—The Secretary shall annually prepare and submit to the appropriate committees of the Congress a report describing the activities carried out under this section during the preceding fiscal year, and including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.''.

SEC. 3. ALTERNATIVE HUMAN PLURIPOTENT STEM CELL RESEARCH.

Part H of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.), as amended by section 2, is further amended by inserting after section 498D the following:

''SEC. 498E. ALTERNATIVE HUMAN PLURIPOTENT STEM CELL RESEARCH.

''(a) IN GENERAL.—In accordance with section 492, the Secretary shall conduct and support basic and applied research to develop techniques for the isolation, derivation, production, or testing of stem cells that, like embryonic stem cells, are capable of producing all or almost all of the cell types of the developing body and may result in

improved understanding of or treatments for diseases and other adverse health conditions, but are not derived from a human embryo.

''(b) GUIDELINES.—Not later than 90 days after the date of the enactment of this section, the Secretary, after consultation with the Director of NIH, shall issue final guidelines to implement subsection (a), that—

''(1) provide guidance concerning the next steps required for additional research, which shall include a determination of the extent to which specific techniques may require additional basic or animal research to ensure that any research involving human cells using these techniques would clearly be consistent with the standards established under this section;

''(2) prioritize research with the greatest potential for near-term clinical benefit; and

''(3) consistent with subsection (a), take into account techniques outlined by the President's Council on Bioethics and any other appropriate techniques and research.

''(c) REPORTING REQUIREMENTS.—Not later than January 1 of each year, the Secretary shall prepare and submit to the appropriate committees of the Congress a report describing the activities carried out under this sec-

tion during the fiscal year, including a description of the research conducted under this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect any policy, guideline, or regulation regarding embryonic stem cell research, human cloning by somatic cell nuclear transfer, or any other research not specifically authorized by this section.

''(e) DEFINITION.—

''(1) IN GENERAL.—In this section, the term 'human embryo' shall have the meaning given such term in the applicable appropriations Act.

''(2) APPLICABLE ACT.—For purposes of paragraph (1), the term 'applicable appropriations Act' means, with respect to the fiscal year in which research is to be conducted or supported under this section, the Act making appropriations for the Department of Health and Human Services for such fiscal year, except that if the Act for such fiscal year does not contain the term referred to in paragraph (1), the Act for the previous fiscal year shall be deemed to be the applicable appropriations Act.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be nec-

essary for each of fiscal years 2010 through 2012, to carry out this section.''.

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