

Executive Order 13435 of June 20, 2007

Expanding Approved Stem Cell Lines in Ethically Responsible Ways

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to provide leadership with respect to research on pluripotent stem cells derived by ethically responsible techniques so that the potential of pluripotent stem cells can be explored without violating human dignity or demeaning human life, it is hereby ordered as follows:

Section 1. *Research on Alternative Sources of Pluripotent Stem Cells.* (a) The Secretary of Health and Human Services (Secretary) shall conduct and support research on the isolation, derivation, production, and testing of stem cells that 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 derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus.

(b) Within 90 days of this order, the Secretary, after such consultation with the Director of the National Institutes of Health (Director), shall issue a plan, including such mechanisms as requests for proposals, requests for applications, program announcements and other appropriate means, to implement subsection (a) of this section, that:

(i) specifies and reflects 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 is clearly consistent with the standards established under this order and applicable law;

(ii) prioritizes research with the greatest potential for clinical benefit;

(iii) takes into account techniques outlined by the President's Council on Bioethics, and any other appropriate techniques and research, provided they clearly meet the standard set forth in subsection (a) of this section;

(iv) renames the "Human Embryonic Stem Cell Registry" the "Human Pluripotent Stem Cell Registry;" and

(v) adds to the registry new human pluripotent stem cell lines that clearly meet the standard set forth in subsection (a) of this section.

(c) Not later than December 31 of each year, the Secretary shall report to the President on the activities carried out under this order during the past fiscal year, including a description of the research carried out or supported by the Department of Health and Human Services, including the National Institutes of Health, and other developments in the science of pluripotent stem cells not derived from human embryos.

Sec. 2. *Policy.* The activities undertaken and supported by and under the direction of the Secretary shall be clearly consistent with the following policies and principles:

(a) the purposes of this order are (i) to direct the Department of Health and Human Services, including the National Institutes of Health, to intensify

peer reviewed research that may result in improved understanding of or treatments for diseases and other adverse health conditions, and (ii) to promote the derivation of human pluripotent stem cell lines from a variety of alternative sources while clearly meeting the standard set forth in section 1(a) of this order;

(b) it is critical to establish moral and ethical boundaries to allow the Nation to move forward vigorously with medical research, while also maintaining the highest ethical standards and respecting human life and human dignity;

(c) the destruction of nascent life for research violates the principle that no life should be used as a mere means for achieving the medical benefit of another;

(d) human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold; and

(e) the Federal Government has a duty to exercise responsible stewardship of taxpayer funds, both supporting important medical research and respecting ethical and moral boundaries.

Sec. 3. Interpretation of this Order. (a) For purposes of this order, the term “human embryo” shall mean any organism, not protected as a human subject under 45 CFR 46 as of the date of this order, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

(b) For purposes of this order, the term “subjecting to harm a human embryo” shall mean subjecting such an embryo to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)) as of the date of this order.

(c) Nothing in this order 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 order, or to forbid the use of existing stem cell lines deemed eligible for other federally funded research in accordance with the presidential policy decision of August 9, 2001, for research specifically authorized by this order.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) This order is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

The White House,

June 20, 2007.