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116TH CONGRESS
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S. 2308

To intensify stem cell research showing evidence of substantial clinical benefit to patients, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 29, 2019

Mr. WICKER (for himself, Mr. LANKFORD, Mrs. HYDE-SMITH, Mr. BLUNT, Mrs. BLACKBURN, Mr. DAINES, Mr. INHOFE, Ms. ERNST, and Mr. CRAMER) 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 intensify stem cell research showing evidence of substantial clinical benefit to patients, and for other purposes.

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 ''Patients First Act of 2019''.

SEC. 2. PURPOSES.

It is the purpose of this Act to—

(1) intensify research that may result in improved understanding of or treatments for diseases and other adverse health conditions;

(2) promote research and human clinical trials using stem cells that are ethically obtained and show evidence of providing clinical benefit for human patients; and

(3) promote the derivation of pluripotent stem cell lines without the creation of human embryos for research purposes and without the destruction or discarding of, or risk of injury to, a human embryo.

SEC. 3. HUMAN STEM CELL RESEARCH AND THERAPY.

(a) AUTHORIZATION.—Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by inserting after section 409J the following:

"SEC. 409K. HUMAN STEM CELL RESEARCH AND THERAPY.

''(a) IN GENERAL.—The Secretary shall conduct and support basic and applied research to develop techniques for the isolation, derivation, production, testing, and human clinical use of stem cells that may result in improved understanding of, or treatments for, diseases and other adverse health conditions, including pluripotent stem cells that have the flexibility of embryonic stem cells (whether or not such pluripotent stem cells have an embryonic source), prioritizing research with the greatest poten-

tial for near-term clinical benefit in human patients, provided that such isolation, derivation, production, testing, or use will not involve—

''(1) the creation of a human embryo for research purposes;

''(2) the destruction of or discarding of, or risk of injury to, a living human embryo; or

''(3) the use of any stem cell, the derivation or provision of which would be inconsistent with the standards under paragraph (1) or (2).

''(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 implementing subsection (a) to ensure that any research (including any clinical trial) supported under subsection (a)—

''(1) is clearly consistent with the standards established in subsection (a) if conducted using human cells, as demonstrated by animal trials or other substantial evidence; and

''(2) is prioritized in terms of potential for near-term clinical benefit in human patients, as indicated by substantial evidence from basic research or by substantial clinical evidence, which may include—

''(A) evidence of improvement in one or more human patients suffering from illness or injury, as documented in reports by professional medical or scientific associations or in peer-reviewed medical or scientific literature; or

''(B) approval for use in human trials by the Food and Drug Administration.

''(c) DEFINITIONS.—In this section:

''(1) HUMAN EMBRYO.—The term 'human embryo' includes any organism, not protected as a human subject under part 46 of title 45, Code of Federal Regulations, as of the date of the enactment of this section, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

''(2) RISK OF INJURY.—The term 'risk of injury' means subjecting a human embryo to risk of injury or death greater than that allowed for research on fetuses in utero under section 46.204(b) of title 45, Code of Federal Regulations (or any successor regulation), or section 498(b) of this Act.''.

(b) PRIORITY SETTING; REPORTS.—Section 492 of the Public Health Service Act (42 U.S.C. 289a) is amended by adding at the end the following:

''(d)(1) With respect to human stem cell research, the Secretary, acting through the Director of NIH, shall give priority to conducting or supporting research in accordance with section 409K.

''(2) At the end of fiscal year 2019 and each subsequent fiscal year, the Secretary shall submit to Congress a report outlining the number of research proposals under section 409K that were peer reviewed, a summary and detailed list of all such research proposals that were not funded, and an explanation of why the proposals did not merit funding. The reports under this paragraph shall be in addition to the reporting on stem cell research included in the triennial report required by section 403.''.

(c) TRIENNIAL REPORTS.—Section 403(a)(5) of the Public Health Service Act (42 U.S.C. 283(a)(5)) is amended—

(1) by redesignating subparagraph (L) as subparagraph (M); and

(2) by inserting after subparagraph (K) the following:

''(L) Stem cells.''.

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