

116TH CONGRESS
1ST SESSION

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Patients First Act of
5 2019”.

6 **SEC. 2. PURPOSES.**

7 It is the purpose of this Act to—

1 (1) intensify research that may result in im-
2 proved understanding of or treatments for diseases
3 and other adverse health conditions;

4 (2) promote research and human clinical trials
5 using stem cells that are ethically obtained and show
6 evidence of providing clinical benefit for human pa-
7 tients; and

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

12 **SEC. 3. HUMAN STEM CELL RESEARCH AND THERAPY.**

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

16 **“SEC. 409K. HUMAN STEM CELL RESEARCH AND THERAPY.**

17 “(a) IN GENERAL.—The Secretary shall conduct and
18 support basic and applied research to develop techniques
19 for the isolation, derivation, production, testing, and
20 human clinical use of stem cells that may result in im-
21 proved understanding of, or treatments for, diseases and
22 other adverse health conditions, including pluripotent stem
23 cells that have the flexibility of embryonic stem cells
24 (whether or not such pluripotent stem cells have an embry-
25 onic source), prioritizing research with the greatest poten-

1 tial for near-term clinical benefit in human patients, pro-
2 vided that such isolation, derivation, production, testing,
3 or use will not involve—

4 “(1) the creation of a human embryo for re-
5 search purposes;

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

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

11 “(b) GUIDELINES.—Not later than 90 days after the
12 date of the enactment of this section, the Secretary, after
13 consultation with the Director of NIH, shall issue final
14 guidelines implementing subsection (a) to ensure that any
15 research (including any clinical trial) supported under
16 subsection (a)—

17 “(1) is clearly consistent with the standards es-
18 tablished in subsection (a) if conducted using human
19 cells, as demonstrated by animal trials or other sub-
20 stantial evidence; and

21 “(2) is prioritized in terms of potential for
22 near-term clinical benefit in human patients, as indi-
23 cated by substantial evidence from basic research or
24 by substantial clinical evidence, which may include—

1 “(A) evidence of improvement in one or
 2 more human patients suffering from illness or
 3 injury, as documented in reports by professional
 4 medical or scientific associations or in peer-re-
 5 viewed medical or scientific literature; or

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

8 “(c) DEFINITIONS.—In this section:

9 “(1) HUMAN EMBRYO.—The term ‘human em-
 10 bryo’ includes any organism, not protected as a
 11 human subject under part 46 of title 45, Code of
 12 Federal Regulations, as of the date of the enactment
 13 of this section, that is derived by fertilization, par-
 14 thenogenesis, cloning, or any other means from one
 15 or more human gametes or human diploid cells.

16 “(2) RISK OF INJURY.—The term ‘risk of in-
 17 jury’ means subjecting a human embryo to risk of
 18 injury or death greater than that allowed for re-
 19 search on fetuses in utero under section 46.204(b)
 20 of title 45, Code of Federal Regulations (or any suc-
 21 cessor regulation), or section 498(b) of this Act.”.

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

1 “(d)(1) With respect to human stem cell research, the
 2 Secretary, acting through the Director of NIH, shall give
 3 priority to conducting or supporting research in accord-
 4 ance with section 409K.

5 “(2) At the end of fiscal year 2019 and each subse-
 6 quent fiscal year, the Secretary shall submit to Congress
 7 a report outlining the number of research proposals under
 8 section 409K that were peer reviewed, a summary and de-
 9 tailed list of all such research proposals that were not
 10 funded, and an explanation of why the proposals did not
 11 merit funding. The reports under this paragraph shall be
 12 in addition to the reporting on stem cell research included
 13 in the triennial report required by section 403.”.

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

17 (1) by redesignating subparagraph (L) as sub-
 18 paragraph (M); and

19 (2) by inserting after subparagraph (K) the fol-
 20 lowing:

21 “(L) Stem cells.”.

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