

116TH CONGRESS
1ST SESSION

H. R. 64

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 3, 2019

Mr. BANKS introduced the following bill; which was referred to the Committee on Energy and Commerce

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—

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

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

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

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

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

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

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

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

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

5 “(3) the use of any stem cell, the derivation or
6 provision of which would be inconsistent with the
7 standards established in paragraph (1) or (2).

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

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

18 “(2) is prioritized in terms of potential for
19 near-term clinical benefit in human patients, as indi-
20 cated by substantial evidence from basic research or
21 by substantial clinical evidence which may include
22 but is not limited to—

23 “(A) evidence of improvement in one or
24 more human patients suffering from illness or
25 injury, as documented in reports by professional

1 medical or scientific associations or in peer-re-
2 viewed medical or scientific literature; or

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

5 “(c) DEFINITIONS.—In this section:

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

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

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

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

1 “(2) At the end of fiscal year 2020 and each subse-
2 quent fiscal year, the Secretary shall submit to the Con-
3 gress a report outlining the number of research proposals
4 under section 409K that were peer reviewed, a summary
5 and detailed list of all such research proposals that were
6 not funded, and an explanation of why the proposals did
7 not merit funding. The reports under this paragraph shall
8 be in addition to the reporting on stem cell research in-
9 cluded in the biennial report required by section 403.”.

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

13 (1) by redesignating subparagraph (L) as sub-
14 paragraph (M); and

15 (2) by inserting after subparagraph (K) the fol-
16 lowing:

17 “(L) Stem cells.”.

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