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(Original Signature of Member)

110TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To amend the Public Health Service Act to provide for human embryonic stem cell research, to direct the National Institutes of Health to issue guidelines for such stem cell research, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Ms. DEGETTE (for herself and Mr. CASTLE) introduced the following bill;  
which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Public Health Service Act to provide for human embryonic stem cell research, to direct the National Institutes of Health to issue guidelines for such stem cell research, 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 “Stem Cell Research  
5 Enhancement Act of 2008”.

1 **SEC. 2. HUMAN EMBRYONIC STEM CELL RESEARCH.**

2 Part H of title IV of the Public Health Service Act  
3 (42 U.S.C. 289 et seq.) is amended by inserting after sec-  
4 tion 498C the following:

5 **“SEC. 498D. HUMAN EMBRYONIC STEM CELL RESEARCH.**

6 “(a) IN GENERAL.—Notwithstanding any other pro-  
7 vision of law (including any regulation or guidance), the  
8 Secretary shall conduct and support research that utilizes  
9 human embryonic stem cells (regardless of the date on  
10 which the stem cells were derived from a human embryo).

11 “(b) ETHICAL REQUIREMENTS.—Human embryonic  
12 stem cells shall be eligible for use in any research con-  
13 ducted or supported by the Secretary if the cells meet each  
14 of the following:

15 “(1) The stem cells were derived from human  
16 embryos that have been donated from in vitro fer-  
17 tilization clinics, were created for the purposes of  
18 fertility treatment, and were in excess of the clinical  
19 need of the individuals seeking such treatment.

20 “(2) Prior to the consideration of embryo dona-  
21 tion and through consultation with the individuals  
22 seeking fertility treatment, it was determined that  
23 the embryos would never be implanted in a woman  
24 and would otherwise be discarded.

25 “(3) The individuals seeking fertility treatment  
26 donated the embryos with written informed consent

1 and without receiving any financial or other induce-  
2 ments to make the donation.”.

3 **SEC. 3. GUIDELINES ON RESEARCH INVOLVING HUMAN**  
4 **STEM CELLS.**

5 Part H of title IV of the Public Health Service Act  
6 (42 U.S.C. 289 et seq.) is further amended by inserting  
7 after section 498D, as inserted by this Act, the following:

8 **“SEC. 498E. GUIDELINES ON RESEARCH INVOLVING HUMAN**  
9 **STEM CELLS.**

10 “(a) IN GENERAL.—Not later than 90 days after the  
11 date of the enactment of this section, the Director of  
12 NIH—

13 “(1) shall issue guidelines on research involving  
14 human embryonic stem cells; and

15 “(2) may issue guidelines on research involving  
16 other human stem cells, as determined to be scientif-  
17 ically warranted by the Director of NIH.

18 “(b) UPDATES.—

19 “(1) IN GENERAL.—Subject to paragraph (2),  
20 the Director of NIH shall review and, as appro-  
21 priate, update the guidelines issued under para-  
22 graphs (1) and (2) of subsection (a) when the Direc-  
23 tor determines that such updates are scientifically  
24 warranted. The Director of NIH may determine the  
25 extent to which such an update applies to ongoing

1 National Institutes of Health conducted- or sup-  
2 ported-research.

3 “(2) FREQUENCY OF UPDATES.—The first up-  
4 date required under paragraph (1), with respect to  
5 guidelines issued under paragraph (1) or (2) of sub-  
6 section (a), shall be made not later than the last day  
7 of the three-year period beginning on the date such  
8 respective guidelines are issued and each subsequent  
9 update to such respective guidelines shall be made  
10 not later than the last day of each subsequent three-  
11 year period.

12 “(c) CONSIDERATION OF OTHER GUIDELINES.—In  
13 developing and updating the guidelines under this section,  
14 the Director of NIH shall, as appropriate, take into con-  
15 sideration guidelines on human stem cell research devel-  
16 oped by nationally- and internationally-recognized sci-  
17 entific organizations.

18 “(d) APPLICATION OF GUIDELINES TO RESEARCH.—

19 “(1) IN GENERAL.—Subject to paragraph (2),  
20 research that is first conducted or supported by the  
21 National Institutes of Health on or after the effec-  
22 tive date of the applicable guidelines under sub-  
23 section (a) shall comply with such guidelines.

24 “(2) EXCEPTION FOR CELLS DERIVED BEFORE  
25 THE EFFECTIVE DATE OF THE GUIDELINES.—The

1 Director of NIH shall determine the extent to which  
2 the guidelines under this section shall apply to re-  
3 search described in paragraph (1) that uses human  
4 stem cells derived before the effective date of such  
5 guidelines.

6 “(e) PUBLIC DISCLOSURE.—The Director of NIH  
7 shall publish the guidelines issued and updated under this  
8 section on the public website of the National Institutes  
9 of Health.”.

10 **SEC. 4. REPORTING REQUIREMENTS.**

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

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

14 and

15 (2) by inserting the following:

16 “(L) Human stem cells.”.

17 **SEC. 5. SENSE OF CONGRESS.**

18 It is the sense of the Congress that—

19 (1) in developing, updating, and implementing  
20 the guidelines under section 498E of the Public  
21 Health Service Act, as added by section 3, the Di-  
22 rector of the National Institutes of Health should  
23 consult with the Commissioner of Food and Drugs;

24 (2) any research using human stem cells, irre-  
25 spective of whether such research is federally fund-

1 ed, should comply with the guidelines under section  
2 498E; and

3 (3) the Commissioner of Food and Drugs  
4 should keep the Director of the National Institutes  
5 of Health informed of the types of human stem cell  
6 and related research that would facilitate the evalua-  
7 tion of the safety or effectiveness of drugs, devices,  
8 and biological products.