

117TH CONGRESS  
1ST SESSION

# S. 288

To reauthorize the Stem Cell Therapeutic and Research Act of 2005, and  
for other purposes.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 8, 2021

Mr. REED (for himself, Mr. BURR, Ms. SMITH, and Mr. SCOTT of South Carolina) 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 reauthorize the Stem Cell Therapeutic and Research Act  
of 2005, 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 “Timely ReAuthoriza-  
5 tion of Necessary Stem-cell Programs Lends Access to  
6 Needed Therapies Act of 2021” or the “TRANSPLANT  
7 Act of 2021”.

1 **SEC. 2. REAUTHORIZATION OF THE C.W. BILL YOUNG CELL**  
 2 **TRANSPLANTATION PROGRAM.**

3 (a) **ADVISORY COUNCIL MEETINGS.**—Subsection (a)  
 4 of section 379 of the Public Health Service Act (42 U.S.C.  
 5 274k) is amended by adding at the end the following new  
 6 paragraph:

7 “(7) The Secretary shall convene the Advisory  
 8 Council at least 2 times each calendar year.”.

9 (b) **INCREASING COLLECTION.**—

10 (1) **TECHNICAL CLARIFICATION.**—Effective as  
 11 if included in the enactment of Public Law 114–104  
 12 (the Stem Cell Therapeutic and Research Reauthor-  
 13 ization Act of 2015), the amendment to section  
 14 379(d)(2)(B) of the Public Health Service Act (42  
 15 U.S.C. 274k(d)(2)(B)) in section 2(a)(2) of Public  
 16 Law 114–104 is amended by inserting “goal of in-  
 17 creasing collections of high quality” before “cord  
 18 blood units,”.

19 (2) **ELIMINATING DEADWOOD.**—Subparagraph  
 20 (B) of section 379(d)(2) of the Public Health Serv-  
 21 ice Act (42 U.S.C. 274k(d)(2)) is amended by strik-  
 22 ing the second and third sentences in such subpara-  
 23 graph.

24 (c) **PERIODIC REVIEW OF STATE OF SCIENCE.**—Sec-  
 25 tion 379 of the Public Health Service Act (42 U.S.C.

1 274k) is amended by adding at the end the following new  
2 subsection:

3 “(o) PERIODIC REVIEW OF STATE OF SCIENCE.—

4 “(1) REVIEW.—Not less frequently than every  
5 2 years, the Secretary, in consultation with the Di-  
6 rector of the National Institutes of Health, the Com-  
7 missioner of Food and Drugs, the Administrator of  
8 the Health Resources and Services Administration,  
9 the Advisory Council, and other stakeholders, where  
10 appropriate given relevant expertise, shall conduct a  
11 review of the state of the science of using adult stem  
12 cells and birthing tissues to develop new types of  
13 therapies for patients, for the purpose of considering  
14 the potential inclusion of such new types of therapies  
15 in the Program.

16 “(2) RECOMMENDATIONS.—Not later than  
17 June 30, 2025, the Secretary shall—

18 “(A) complete the second review required  
19 by paragraph (1); and

20 “(B) informed by such review, submit to  
21 the Committee on Health, Education, Labor,  
22 and Pensions of the Senate and the Committee  
23 on Energy and Commerce of the House of Rep-  
24 resentatives recommendations on the appro-

1           priateness of the inclusion of new types of  
2           therapies in the Program.”.

3           (d) **AUTHORIZATION OF APPROPRIATIONS.**—Section  
4 379B of the Public Health Service Act (42 U.S.C. 274m)  
5 is amended by striking “\$33,000,000 for fiscal year 2015  
6 and \$30,000,000 for each of fiscal years 2016 through  
7 2020” and inserting “\$31,000,000 for each of fiscal years  
8 2022 through 2026”.

9 **SEC. 3. CORD BLOOD INVENTORY.**

10          Subsection (g) of section 2 of the Stem Cell Thera-  
11 peutic and Research Act of 2005 (42 U.S.C. 274k note)  
12 is amended to read as follows:

13          “(g) **AUTHORIZATION OF APPROPRIATIONS.**—To  
14 carry out this section, there is authorized to be appro-  
15 priated \$23,000,000 for each of fiscal years 2022 through  
16 2026.”.

17 **SEC. 4. ADVANCING THE FIELD OF REGENERATIVE MEDI-**  
18 **CINE.**

19          Section 402 of the Public Health Service Act (42  
20 U.S.C. 282) is amended by adding at the end the fol-  
21 lowing:

22          “(o) **REGENERATIVE MEDICINE.**—The Director of  
23 NIH shall, as appropriate, continue to consult with the  
24 directors of relevant institutes and centers of the National  
25 Institutes of Health, other relevant experts from such in-

stitutes and centers, and relevant experts within the Food and Drug Administration, to further the field of regenerative medicine using adult stem cells, including autologous stem cells, therapeutic tissue engineering products, human cell and tissue products, human gene therapies, and genetically modified cells.”.

**SEC. 5. GAO REPORT ON REGENERATIVE MEDICINE WORKFORCE.**

Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that assesses a specialized health care workforce in the field of regenerative medicine. The report shall include—

(1) an overview of the current employment levels, in both commercial and academic settings, for—

(A) positions necessary for the collection and transplantation of stem cell therapeutics, including bone marrow and cord blood; and

(B) positions in the field of regenerative medicine using adult stem cells and related to product development;

1           (2) the identification of gaps, if any, in the pro-  
2       jected workforce capacity for—

3                   (A) positions described in paragraph  
4       (1)(A); and

5                   (B) the field of regenerative medicine using  
6       adult stem cells, including workforce gaps re-  
7       lated to the development of new cellular thera-  
8       pies using adult stem cells;

9           (3) an overview of the availability of training  
10       programs related to the development, refinement,  
11       and utilization of adult stem cells, including training  
12       on good manufacturing practices for such activities,  
13       and the performance of such programs; and

14           (4) recommendations, if any, for improving the  
15       workforce capacity related to—

16                   (A) the positions described in paragraph  
17       (1)(A); or

18                   (B) the field of regenerative medicine using  
19       adult stem cells.

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