

116TH CONGRESS
2D SESSION

S. 4672

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 23, 2020

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

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 2020” or the “TRANSPLANT
7 Act of 2020”.

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 Advisory Council shall meet not less
8 frequently than 2 times per 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—

17 (A) by inserting “through” before “remote
18 collection,”; and

19 (B) by inserting “goal of increasing collec-
20 tions of high quality” before “cord blood
21 units,”.

22 (2) **TECHNICAL UPDATE.**—Subparagraph (B)
23 of section 379(d)(2) of the Public Health Service
24 Act (42 U.S.C. 274k(d)(2)) is amended by striking
25 the second and third sentences in such subpara-
26 graph.

1 (c) PERIODIC REVIEW OF STATE OF SCIENCE.—Sec-
2 tion 379 of the Public Health Service Act (42 U.S.C.
3 274k) is amended by adding at the end the following:

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

5 “(1) REVIEW.—The Secretary, in consultation
6 with the Director of the National Institutes of
7 Health, the Commissioner of Food and Drugs, the
8 Administrator of the Health Resources and Services
9 Administration, the Advisory Council, and other
10 stakeholders, where appropriate given relevant ex-
11 pertise, shall conduct a review of the state of the
12 science of using adult stem cells and birth tissue
13 products to develop new types of therapies for pa-
14 tients, for the purpose of considering the potential
15 inclusion of such new types of therapies in the Pro-
16 gram.

17 “(2) RECOMMENDATIONS.—Not later than
18 June 30, 2023, and every 3 years thereafter, the
19 Secretary shall—

20 “(A) complete the review required by para-
21 graph (1); and

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

1 representatives recommendations on the appro-
 2 priateness of the inclusion of new types of
 3 therapies in the Program.”.

4 (d) AUTHORIZATION OF APPROPRIATIONS.—Section
 5 379B of the Public Health Service Act (42 U.S.C. 274m)
 6 is amended by striking “\$33,000,000 for fiscal year 2015
 7 and \$30,000,000 for each of fiscal years 2016 through
 8 2020” and inserting “\$30,000,000 for each of fiscal years
 9 2021 through 2025”.

10 **SEC. 3. CORD BLOOD INVENTORY.**

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

14 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
 15 carry out this section, there is authorized to be appro-
 16 priated \$23,000,000 for each of fiscal years 2021 through
 17 2025.”.

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

20 (a) NATIONAL INSTITUTES OF HEALTH.—Section
 21 402 of the Public Health Service Act (42 U.S.C. 282) is
 22 amended by adding at the end the following:

23 “(o) REGENERATIVE MEDICINE.—The Director of
 24 NIH shall, as appropriate, continue to consult with the
 25 directors of relevant institutes and centers of the National

1 Institutes of Health, other relevant experts from such in-
2 stitutes and centers, and relevant experts within the Food
3 and Drug Administration, to further the field of regenera-
4 tive medicine using adult stem cells, including autologous
5 stem cells, therapeutic tissue engineering products, human
6 cell and tissue products, human gene therapies, and ge-
7 netically modified cells.”.

8 (b) GAO REPORT.—Not later than 2 years after the
9 date of enactment of this Act, the Comptroller General
10 of the United States shall submit to the Committee on
11 Health, Education, Labor, and Pensions of the Senate and
12 the Committee on Energy and Commerce of the House
13 of Representatives a report that assesses the workforce re-
14 lated to the C.W. Bill Young Cell Transplantation Pro-
15 gram established under section 379 of the Public Health
16 Service Act (42 U.S.C. 274k). The report shall include—

17 (1) an overview of the current employment lev-
18 els, in both commercial and academic settings, for—

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

22 (B) positions in the field of regenerative
23 medicine using adult stem cells and related to
24 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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