

116TH CONGRESS
2^D SESSION

H. R. 4764

IN THE SENATE OF THE UNITED STATES

OCTOBER 1, 2020

Received

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Timely ReAuthoriza-
3 tion of Necessary Stem-cell Programs Lends Access to
4 Needed Therapies Act of 2020” or the “TRANSPLANT
5 Act of 2020”.

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

8 (a) **ADVISORY COUNCIL MEETINGS.**—Subsection (a)
9 of section 379 of the Public Health Service Act (42 U.S.C.
10 274k) is amended by adding at the end the following new
11 paragraph:

12 “(7) The Secretary shall convene the Advisory
13 Council at least two times each calendar year.”.

14 (b) **INCREASING COLLECTION.**—

15 (1) **TECHNICAL CLARIFICATION.**—Effective as
16 if included in the enactment of Public Law 114–104
17 (the Stem Cell Therapeutic and Research Reauthor-
18 ization Act of 2015), the amendment to section
19 379(d)(2)(B) of the Public Health Service Act (42
20 U.S.C. 274k(d)(2)(B)) in section 2(a)(2) of Public
21 Law 114–104 is amended by inserting “goal of in-
22 creasing collections of high quality” before “cord
23 blood units,”.

24 (2) **ELIMINATING DEADWOOD.**—Subparagraph
25 (B) of section 379(d)(2) of the Public Health Serv-
26 ice Act (42 U.S.C. 274k(d)(2)) is amended by strik-

1 ing the second and third sentences in such subpara-
2 graph.

3 (c) PERIODIC REVIEW OF STATE OF SCIENCE.—Sec-
4 tion 379 of the Public Health Service Act (42 U.S.C.
5 274k) is amended by adding at the end the following new
6 subsection:

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

8 “(1) REVIEW.—Not less than every two years,
9 the Secretary, in consultation with the Director of
10 the National Institutes of Health, the Commissioner
11 of Food and Drugs, the Administrator of the Health
12 Resources and Services Administration, the Advisory
13 Council, and other stakeholders, where appropriate
14 given relevant expertise, shall conduct a review of
15 the state of the science of using adult stem cells and
16 birthing tissues to develop new types of therapies for
17 patients, for the purpose of considering the potential
18 inclusion of such new types of therapies in the Pro-
19 gram.

20 “(2) RECOMMENDATIONS.—Not later than
21 June 30, 2024, the Secretary shall—

22 “(A) complete the second review required
23 by paragraph (1); and

24 “(B) informed by such review, submit to
25 the Committee on Health, Education, Labor,

1 and Pensions of the Senate and the Committee
2 on Energy and Commerce of the House of Rep-
3 resentatives recommendations on the appro-
4 priateness of the inclusion of new types of
5 therapies in the Program.”.

6 (d) AUTHORIZATION OF APPROPRIATIONS.—Section
7 379B of the Public Health Service Act (42 U.S.C. 274m)
8 is amended by striking “\$33,000,000 for fiscal year 2015
9 and \$30,000,000 for each of fiscal years 2016 through
10 2020” and inserting “\$30,000,000 for each of fiscal years
11 2021 through 2025”.

12 **SEC. 3. CORD BLOOD INVENTORY.**

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

16 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
17 carry out this section, there is authorized to be appro-
18 priated \$23,000,000 for each of fiscal years 2021 through
19 2025.”.

20 **SEC. 4. ADVANCING THE FIELD OF REGENERATIVE MEDI-**
21 **CINE.**

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

1 “(o) REGENERATIVE MEDICINE.—The Director of
2 NIH shall, as appropriate, continue to consult with the
3 directors of relevant institutes and centers of the National
4 Institutes of Health, other relevant experts from such in-
5 stitutes and centers, and relevant experts within the Food
6 and Drug Administration, to further the field of regenera-
7 tive medicine using adult stem cells, including autologous
8 stem cells, therapeutic tissue engineering products, human
9 cell and tissue products, human gene therapies, and ge-
10 netically modified cells.”.

11 **SEC. 5. GAO REPORT ON REGENERATIVE MEDICINE WORK-**
12 **FORCE.**

13 Not later than 2 years after the date of enactment
14 of this Act, the Comptroller General of the United States
15 shall submit to the Committee on Health, Education,
16 Labor, and Pensions of the Senate and the Committee on
17 Energy and Commerce of the House of Representatives
18 a report that assesses the national blood stem cell work-
19 force, including those related to the C.W. Bill Young Cell
20 Transplantation Program established under section 379 of
21 the Public Health Service Act (42 U.S.C. 274k). The re-
22 port shall include—

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

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

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

7 (C) Federal funding for extramural stem
8 cell programs;

9 (2) an overview of the current employment lev-
10 els in Federal stem cell programs, including the
11 scope of, staffing models of, and vacancies within
12 such programs;

13 (3) the identification of gaps, if any, in the pro-
14 jected workforce capacity for—

15 (A) positions described in paragraph
16 (1)(A); and

17 (B) the field of regenerative medicine using
18 adult stem cells, including workforce gaps re-
19 lated to the development of new cellular thera-
20 pies using adult stem cells;

21 (4) an overview of the availability of training
22 programs related to the development, refinement,
23 and utilization of adult stem cells, including training
24 on good manufacturing practices for such activities,
25 and the performance of such programs; and

1 (5) recommendations, if any, for improving the
2 workforce capacity related to—

3 (A) the positions described in paragraph
4 (1)(A); or

5 (B) the field of regenerative medicine using
6 adult stem cells.

Passed the House of Representatives September 30,
2020.

Attest: CHERYL L. JOHNSON,
Clerk.