

117TH CONGRESS
1ST SESSION

H. R. 941

IN THE SENATE OF THE UNITED STATES

APRIL 19, 2021

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

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 2021” or the “TRANSPLANT
5 Act of 2021”.

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 frequently than every
9 2 years, the Secretary, in consultation with the Di-
10 rector of the National Institutes of Health, the Com-
11 missioner of Food and Drugs, the Administrator of
12 the Health Resources and Services Administration,
13 the Advisory Council, and other stakeholders, where
14 appropriate given relevant expertise, shall conduct a
15 review of the state of the science of using adult stem
16 cells and birthing tissues to develop new types of
17 therapies for patients, for the purpose of considering
18 the potential inclusion of such new types of therapies
19 in the Program.

20 “(2) RECOMMENDATIONS.—Not later than
21 June 30, 2025, 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 “\$31,009,000 for each of fiscal years
11 2022 through 2026”.

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 2022 through
19 2026.”.

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 a specialized health care workforce
19 in the field of regenerative medicine. The report shall in-
20 clude—

- 21 (1) an overview of the current employment lev-
22 els, in both commercial and academic settings, for—
23 (A) positions necessary for the collection
24 and transplantation of stem cell therapeutics,
25 including bone marrow and cord blood; and

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

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

6 (A) positions described in paragraph
7 (1)(A); and

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

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

17 (4) recommendations, if any, for improving the
18 workforce capacity related to—

19 (A) the positions described in paragraph
20 (1)(A); or

1 (B) the field of regenerative medicine using
2 adult stem cells.

Passed the House of Representatives April 15, 2021.

Attest: CHERYL L. JOHNSON,
Clerk.