

In the Senate of the United States,

December 11, 2020.

Resolved, That the bill from the House of Representatives (H.R. 4764) entitled “An Act to reauthorize the Stem Cell Therapeutic and Research Act of 2005, and for other purposes.”, do pass with the following

AMENDMENT:

Strike all after the enacting clause and insert the following:

1 ***SECTION 1. SHORT TITLE.***

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

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

8 *(a) ADVISORY COUNCIL MEETINGS.—Subsection (a) of*
9 *section 379 of the Public Health Service Act (42 U.S.C.*

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

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

5 *(b) INCREASING COLLECTION.—*

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

15 (2) *ELIMINATING DEADWOOD.—Subparagraph*
16 *(B) of section 379(d)(2) of the Public Health Service*
17 *Act (42 U.S.C. 274k(d)(2)) is amended by striking the*
18 *second and third sentences in such subparagraph.*

19 (c) *PERIODIC REVIEW OF STATE OF SCIENCE.—Sec-*
20 *tion 379 of the Public Health Service Act (42 U.S.C. 274k)*
21 *is amended by adding at the end the following new sub-*
22 *section:*

23 “(o) *PERIODIC REVIEW OF STATE OF SCIENCE.—*

24 (1) *REVIEW.—Not less than every two years,*
25 *the Secretary, in consultation with the Director of the*

1 *National Institutes of Health, the Commissioner of*
2 *Food and Drugs, the Administrator of the Health Re-*
3 *sources and Services Administration, the Advisory*
4 *Council, and other stakeholders, where appropriate*
5 *given relevant expertise, shall conduct a review of the*
6 *state of the science of using adult stem cells and birth-*
7 *ing tissues to develop new types of therapies for pa-*
8 *tients, for the purpose of considering the potential in-*
9 *clusion of such new types of therapies in the Program.*

10 “(2) *RECOMMENDATIONS.*—Not later than June
11 30, 2024, the Secretary shall—

12 “(A) complete the second review required by
13 paragraph (1); and

14 “(B) informed by such review, submit to the
15 *Committee on Health, Education, Labor, and*
16 *Pensions of the Senate and the Committee on*
17 *Energy and Commerce of the House of Rep-*
18 *resentatives recommendations on the appro-*
19 *riateness of the inclusion of new types of thera-*
20 *pies in the Program.”.*

21 (d) *AUTHORIZATION OF APPROPRIATIONS.*—Section
22 379B of the Public Health Service Act (42 U.S.C. 274m)
23 is amended by striking “\$33,000,000 for fiscal year 2015
24 and \$30,000,000 for each of fiscal years 2016 through 2020”

1 *and inserting “\$30,000,000 for each of fiscal years 2021*
2 *through 2025”.*

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

4 *Subsection (g) of section 2 of the Stem Cell Therapeutic*
5 *and Research Act of 2005 (42 U.S.C. 274k note) is amended*
6 *to read as follows:*

7 *“(g) AUTHORIZATION OF APPROPRIATIONS.—To carry*
8 *out this section, there is authorized to be appropriated*
9 *\$23,000,000 for each of fiscal years 2021 through 2025.”.*

10 **SEC. 4. ADVANCING THE FIELD OF REGENERATIVE MEDI-**
11 **CINE.**

12 *Section 402 of the Public Health Service Act (42*
13 *U.S.C. 282) is amended by adding at the end the following:*

14 *“(o) REGENERATIVE MEDICINE.—The Director of NIH*
15 *shall, as appropriate, continue to consult with the directors*
16 *of relevant institutes and centers of the National Institutes*
17 *of Health, other relevant experts from such institutes and*
18 *centers, and relevant experts within the Food and Drug Ad-*
19 *ministration, to further the field of regenerative medicine*
20 *using adult stem cells, including autologous stem cells,*
21 *therapeutic tissue engineering products, human cell and tis-*
22 *sue products, human gene therapies, and genetically modi-*
23 *fied cells.”.*

1 **SEC. 5. GAO REPORT ON REGENERATIVE MEDICINE WORK-**
2 **FORCE.**

3 *Not later than 2 years after the date of enactment of*
4 *this Act, the Comptroller General of the United States shall*
5 *submit to the Committee on Health, Education, Labor, and*
6 *Pensions of the Senate and the Committee on Energy and*
7 *Commerce of the House of Representatives a report that as-*
8 *sesses a specialized health care workforce in the field of re-*
9 *generative medicine. The report shall include—*

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

12 *(A) positions necessary for the collection*
13 *and transplantation of stem cell therapeutics, in-*
14 *cluding bone marrow and cord blood; and*

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

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

20 *(A) positions described in paragraph*
21 *(1)(A); and*

22 *(B) the field of regenerative medicine using*
23 *adult stem cells, including workforce gaps related*
24 *to the development of new cellular therapies*
25 *using adult stem cells;*

1 (3) *an overview of the availability of training*
2 *programs related to the development, refinement, and*
3 *utilization of adult stem cells, including training on*
4 *good manufacturing practices for such activities, and*
5 *the performance of such programs; and*

6 (4) *recommendations, if any, for improving the*
7 *workforce capacity related to—*

8 (A) *the positions described in paragraph*
9 (1)(A); *or*

10 (B) *the field of regenerative medicine using*
11 *adult stem cells.*

Attest:

Secretary.

116TH CONGRESS
2^D SESSION

H.R. 4764

AMENDMENT