Suspend the Rules and Pass the Bill, H.R. 4764, with an Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

116TH CONGRESS
1ST SESSION

H. R. 4764

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 18, 2019

Ms. MATSUI (for herself, Mr. BILIRAKIS, and Ms. PINGREE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2020'' or the ''TRANSPLANT Act of 2020''.

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

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

''(7) The Secretary shall convene the Advisory Council at least two times each calendar year.''.

(b) INCREASING COLLECTION.—

(1) TECHNICAL CLARIFICATION.—Effective as if included in the enactment of Public Law 114–104 (the Stem Cell Therapeutic and Research Reauthorization Act of 2015), the amendment to section 379(d)(2)(B) of the Public Health Service Act (42 U.S.C. 274k(d)(2)(B)) in section 2(a)(2) of Public Law 114–104 is amended by inserting ''goal of increasing collections of high quality'' before ''cord blood units,''.

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

(c) PERIODIC REVIEW OF STATE OF SCIENCE.—Section 379 of the Public Health Service Act (42 U.S.C.

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

''(o) PERIODIC REVIEW OF STATE OF SCIENCE.—

''(1) REVIEW.—Not less than every two years, the Secretary, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Administrator of the Health Resources and Services Administration, the Advisory Council, and other stakeholders, where appropriate given relevant expertise, shall conduct a review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering the potential inclusion of such new types of therapies in the Program.

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

''(A) complete the second review required by paragraph (1); and

''(B) informed by such review, 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 recommendations on the appro-

priateness of the inclusion of new types of therapies in the Program.''.

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

SEC. 3. CORD BLOOD INVENTORY.

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

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $23,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 4. ADVANCING THE FIELD OF REGENERATIVE MEDICINE.

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

''(o) REGENERATIVE MEDICINE.—The Director of NIH shall, as appropriate, continue to consult with the directors of relevant institutes and centers of the National 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 the national blood stem cell workforce, including those related to the C.W. Bill Young Cell Transplantation Program established under section 379 of the Public Health Service Act (42 U.S.C. 274k). 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;

(2) the identification of gaps, if any, in the projected workforce capacity for—

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

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

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

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

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

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