

PUBLIC LAW 114-104—DEC. 18, 2015

**STEM CELL THERAPEUTIC AND RESEARCH
REAUTHORIZATION ACT OF 2015**

Public Law 114–104
114th Congress

An Act

Dec. 18, 2015
[H.R. 2820]

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

Stem Cell
Therapeutic and
Research
Reauthorization
Act of 2015.

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 “Stem Cell Therapeutic and Research Reauthorization Act of 2015”.

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

(a) IN GENERAL.—Section 379(d)(2)(B) of the Public Health Service Act (42 U.S.C. 274k(d)(2)(B)) is amended—

- (1) by striking “remote collection” and inserting “collection”;
- and
- (2) by inserting “including remote collection,” after “cord blood units,”.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 379B of the Public Health Service Act (42 U.S.C. 274m) is amended—

- (1) by striking “\$30,000,000 for each of fiscal years 2011 through 2014 and”; and
- (2) by inserting “and \$30,000,000 for each of fiscal years 2016 through 2020” before the period at the end.

Consultation.

(c) SECRETARY REVIEW ON STATE OF SCIENCE.—The Secretary of Health and Human Services, in consultation with the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Administrator of the Health Resources and Services Administration, including the Advisory Council on Blood Stem Cell Transplantation established under section 379(a) of the Public Health Service Act (42 U.S.C. 274k(a)), 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 C.W. Bill Young Cell Transplantation Program (established under such section 379) in addition to the continuation of ongoing activities. Not later than June 30, 2019, the Secretary 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 recommendations on the appropriateness of such new types of therapies for inclusion in the C.W. Bill Young Cell Transplantation Program.

Deadline.
Recommendations.

SEC. 3. CORD BLOOD INVENTORY.

Section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) is amended—

(1) in subsection (a), by striking “one-time”;

(2) by striking subsection (c);

(3) by redesignating subsections (d) through (h) as subsections (c) through (g), respectively;

(4) in subsection (d) (as so redesignated)—

(A) in paragraph (1), by striking “paragraphs (2) and (3)” and inserting “paragraphs (2), (3), and (4)”;

(B) in paragraph (2)(B), by striking “subsection (d)” and inserting “subsection (c)”; and

(C) by adding at the end the following:

“(4) CONSIDERATION OF BEST SCIENCE.—The Secretary shall take into consideration the best scientific information available in order to maximize the number of cord blood units available for transplant when entering into contracts under this section, or when extending a period of funding under such a contract under paragraph (2).” Contracts.

“(5) CONSIDERATION OF BANKED UNITS OF CORD BLOOD.—” Contracts.

In extending contracts pursuant to paragraph (3), and determining new allocation amounts for the next contract period or contract extension for such cord blood bank, the Secretary shall take into account the number of cord blood units banked in the National Cord Blood Inventory by a cord blood bank during the previous contract period, in addition to consideration of the ability of such cord blood bank to increase the collection and maintenance of additional, genetically diverse cord blood units.”;

(5) in subsection (f) (as so redesignated)—

(A) by striking paragraph (4); and

(B) by redesignating paragraphs (5) and (6) as paragraphs (4) and (5), respectively; and

(6) in subsection (g) (as so redesignated)—

(A) in paragraph (1)—

(i) by striking “\$23,000,000 for each of fiscal years 2011 through 2014 and”; and

(ii) by inserting “and \$23,000,000 for each of fiscal years 2016 through 2020” before the period at the end; and

(B) by striking paragraph (2).

SEC. 4. DETERMINATION ON THE DEFINITION OF HUMAN ORGAN.

Deadline.

Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue determinations with respect to the inclusion of peripheral blood stem cells and umbilical cord blood in the definition of human organ.

Approved December 18, 2015.

LEGISLATIVE HISTORY—H.R. 2820:

HOUSE REPORTS: No. 114–242 (Comm. on Energy and Commerce).
CONGRESSIONAL RECORD, Vol. 161 (2015):

Sept. 8, considered and passed House.

Dec. 9, considered and passed Senate, amended.

Dec. 16, House concurred in Senate amendment.

