Bill Cassidy, M.D.

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

S. 4109

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Stem Cell Therapeutic and Research Reauthorization Act of 2026".

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

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

(1) by striking "appropriated $31,009,000" and inserting the following: "appropriated—

"(1) $31,009,000";

(2) in paragraph (1), as so inserted, by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(2) $33,009,000 for each of fiscal years 2027 through 2031.".

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 "the inventory goal of at least 150,000 new units of high-quality cord blood" and inserting "a sufficient supply, as determined by the Secretary, of high-quality cord blood units";

(2) in subsection (e)—

(A) in paragraph (2), by striking "in perpetuity or"; and

(B) by amending paragraph (5) to read as follows:

"(5) agree to the terms described in subsection (e).";

(3) in subsection (d)—

(A) in paragraph (1), by striking "paragraph (2)" and inserting "paragraphs (2) and (4)"; and

(B) in paragraph (4)—

(i) in the heading, by striking "SCIENCE" and inserting "AVAILABLE SCIENTIFIC AND CLINICAL EVIDENCE"; and

(ii) by striking "the best scientific information available in order to maximize the number of cord blood units available" and inserting "current scientific and clinical information in order to maximize the availability of high-quality cord blood units meeting applicable clinical and quality standards";

(4) by redesignating subsections (e) through (g) as subsections (g) through (i), respectively;

(5) by inserting after subsection (d) the following:

"(e) TRANSFER OF UNITS.—If the Secretary determines through an assessment, or through petition by a qualified cord blood bank, that a cord blood bank is no longer operational, does not meet clinical and quality standards informed by current scientific and clinical information, does not meet the requirements for an extension under subsection (d), or does not meet the requirements of section 379(d)(4) of the Public Health Service Act, and as a result may not distribute the units, the Secretary may transfer the units collected by such cord blood bank pursu-

ant to this section to another qualified cord blood bank or entity approved by the Secretary to ensure continued availability of high-quality cord blood units.

"(f) INVENTORY MANAGEMENT.—

"(1) IN GENERAL.—The Secretary, in consultation with the Advisory Council on Blood Stem Cell Transplantation as appropriate, shall manage the size and composition of the National Cord Blood Inventory to maximize clinical utility, ensure genetic diversity, and promote the efficient use of Federal resources.

"(2) CONSIDERATIONS.—In carrying out paragraph (1), the Secretary may—

"(A) on the initiative of the Secretary or upon petition by a qualified cord blood bank, make determinations regarding the continued storage of cord blood units based on the best available scientific and clinical evidence; and

"(B) prioritize the collection, retention, or disposition of cord blood units based on scientific, clinical, or operational considerations, as the Secretary determines appropriate.";

(6) in subsection (h), as so redesignated—

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

(B) by inserting after paragraph (3) the following:

"(4) The term 'high-quality cord blood unit' means a unit of cord blood that meets current industry standards and requirements of the Food and Drug Administration."; and

(7) in subsection (i), as so redesignated, by striking "2022 through 2026" and inserting "2027 through 2031".

SEC. 4. PERIODIC REVIEW OF STATE OF SCIENCE UNDER THE NATIONAL PROGRAM.

Section 379(o) of the Public Health Service Act (42 U.S.C. 274k(o))—

(1) in paragraph (1)—

(A) by striking "Not less" and inserting "Beginning 1 year after the date of enactment of the Stem Cell Therapeutic and Research Reauthorization Act of 2026, not less"; and

(B) by striking "and birthing tissues" and inserting ", high-quality cord blood units (as defined in section 2(h) of the Stem Cell Therapeutic and Research Act of 2005), and other emergent technologies"; and

(2) in paragraph (2), by striking "June 30, 2025" and inserting "3 years after the date of en-

actment of the Stem Cell Therapeutic and Research Reauthorization Act of 2026".