BOM16344

S.L.C.

AMENDMENT NO. 1 Calendar No. _____

Purpose: To amend the Federal Food, Drug, and Cosmetic Act with respect to cellular therapies.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 2700

(title) _____

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Kirk (for himself and Mrs. Collins)

Viz:

At the appropriate place, insert the following:

TITLE ____—REGROW ACT

SECTION ___1. SHORT TITLE.

This title may be cited as the "Reliable and Effective Growth for Regenerative Health Options that Improve Wellness" or the "REGROW Act".

SEC. ___2. CELLULAR AND TISSUE THERAPEUTICS.

(a) CURRENT PATHWAYS.—Nothing in this title, or the amendments made by this title, shall be applied or interpreted as restricting or otherwise modifying any pathway to market which is (as of the day immediately before the date enactment of this title) provided under regula-

tions promulgated by the Food and Drug Administration, including pathways under sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 264).

(b) APPROVAL FOR THERAPIES.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by inserting after section 351A the following:

"SEC. 351B. APPROVAL FOR CELLULAR AND TISSUE THERAPEUTICS.

"(a) PROGRAM ESTABLISHED.—Not later than 2 years after the date of enactment of this section, the Secretary shall establish a program to conditionally approve a cellular or tissue therapeutic product if the sponsor of such product demonstrates preliminary clinical evidence of safety, and a reasonable expectation of effectiveness, as determined by the Secretary, as part of the sponsor's phase I and phase II clinical trials.

"(b) CONDITIONAL APPROVAL OF CELLULAR OR TISSUE THERAPEUTIC.—

"(1) IN GENERAL.—A conditionally approved cellular or tissue therapeutic product under subsection (a) shall, for a conditional use period described in paragraph (3), be manufactured, introduced into interstate commerce, and used consistent with the regulations in effect at the time of such

use, including good manufacturing practices, without the approval of an application under section 351(a), if each of the elements described in subsection (c) applies.

"(2) FULL APPLICATION FOR APPROVAL.—The sponsor of the conditionally approved product shall, not later than 5 years after the date of the conditional approval, prepare and submit an application for full approval of such product under section 351(a), demonstrating potency, purity, safety, and efficacy.

"(3) CONDITIONAL USE PERIOD.—Subject to subsection (f), the Secretary shall permit the manufacture, introduction into interstate commerce, and use of such conditionally approved product for a conditional use period of 5 years, except that if the Secretary completes a review of the application for full approval of such product under section 351(a) and makes a determination not to approve the application, the conditional use period for the product shall terminate at that time.

"(c) REQUIREMENTS FOR A CONDITIONALLY APPROVED PRODUCT.—A cellular or tissue therapeutic product shall only receive conditional approval under this section if each of the following apply:

"(1) Such cells or tissues are adult human cells or tissues.

"(2) Such cells or tissues have been evaluated to examine immunogenicity and do not provoke a significant unintended immune response in the recipient.

"(3) Such cells or tissues are—

"(A) minimally manipulated for a non-homologous use; or

"(B) more-than-minimally manipulated for a homologous or non-homologous use, but are not genetically modified.

"(4) Such cells or tissues are produced for a specific indication.

"(5) Such cells or tissues help achieve or restore function and have the potential to provide a benefit over the existing standard of care.

"(6) Data regarding safety and effectiveness shall be collected as required by the post-conditional approval commitments determined by the Secretary at the time of conditional approval.

"(7) During the conditional approval period, and before approval of an application under section 351(a), the sponsor shall prepare and submit to the Secretary—

"(A) annual reports on the progress of achieving the post-conditional approval commitments; and

"(B) adverse event reports containing all the information required for approved biological products.

"(8) The sponsor has submitted an application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for the treatment of patients during the 5-year conditional use period.

"(9) The sponsor has not previously received conditional approval for such product for the same indication.

"(d) INFORMED USE.—The individual administering a product approved under subsection (b) shall inform each individual who uses such product in a written informed consent form signed by the individual user that—

"(1) the product has been conditionally approved based on studies in a limited population, without proof of efficacy;

"(2) the Secretary is requiring additional studies of the product; and

"(3) the Secretary may withdraw conditional approval of the product at any time.

"(e) STEM CELL BANKING.—To be eligible to provide cells for the uses described under subsection (b), public and private cord blood banks, tissue banks, and bone marrow repositories shall be in full compliance with good tissue practice requirements under part 1271 of title 21, Code of Federal Regulations, (or successor regulations), as applicable.

"(f) WITHDRAWAL OF CONDITIONAL APPROVAL.—The Secretary shall, after due notice and opportunity for an informal hearing to the sponsor, issue an order withdrawing conditional approval of a cellular or tissue therapeutic product under this section if the Secretary finds, on the basis of new information before the Secretary with respect to such product, evaluated together with the evidence available to the Secretary at the time such product was conditionally approved, that there is not a reasonable expectation that such product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.".

SEC. ___3. DEVICES USED IN RECOVERY, PROCESSING, AND DELIVERY OF CELLULAR AND TISSUE THERAPEUTICS.

(a) CLEARANCE.—Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is amended—

(1) in paragraph (1), by striking ", and" and inserting ";":

(2) in paragraph (2), by striking the period and inserting "; and"; and

(3) by inserting after paragraph (2) the following:

"(3) in the case of a cellular or tissue therapeutic product described in section 351B(a) of the Public Health Service Act, the general function of the device used for the recovery, isolation, processing, or delivery of such product.".

(b) CLEARANCE OR APPROVAL OF CELLULAR THERAPIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515A the following:

"SEC. 515B. CLASSIFICATION OF CELLULAR AND TISSUE THERAPEUTICS.

"Clearance or approval of a device for harvesting, delivery, or processing of cellular or tissue therapeutics described in section 351B(a) of the Public Health Service

Act shall be based on in vitro performance testing and not in vivo human clinical trials, as appropriate. The Secretary shall classify devices in accordance with section 513, focusing on the general use of such devices for harvesting, delivery, or processing cells and sustaining the viability and functions of the cells in vivo. The classification regulation shall not require that such devices be cleared under section 510(k) or approved under section 515 for use with only specific types of cells or for specific uses unless unique to the intended use of the device. If the Secretary determines that no predicate exists, or that a device classified as class III is sufficiently low risk to justify a lower classification, the Secretary shall apply the procedure outlined in section 513(f)(2) to permit the review and marketing of the device.".

(c) COMBINATION PRODUCTS.—Section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(1)) is amended—

(1) in subparagraph (B), by striking "or";

(2) in subparagraph (C), by striking the period and inserting ", or"; and

(3) by adding at the end the following:

"(D) cellular components, the agency center charged with premarket review of biological products shall have primary jurisdiction.".

SEC. ___4. GUIDANCE; AMENDED REGULATIONS.

(a) GUIDANCE.—Within 1 year of the date of enactment of this title, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue draft guidance on clarifying the requirements with respect to cellular or tissue therapeutic products, as set forth in section 351B of the Public Health Service Act, as added by section ____2, and devices used in harvesting, processing, or delivery of cellular or tissue therapeutic products described in section 351B(a), as set forth in section 510(k)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)(3)) and section 515B of such Act, as added by section ____3(b). The Secretary shall issue final guidance not later than 180 days after the close of the comment period (including any extensions of such period) for the draft guidance. Such comment period may not exceed 60 days.

(b) AMENDED REGULATIONS.—

(1) IN GENERAL.—If the Secretary determines that it is appropriate to amend the regulations under title 21, Code of Federal Regulations, in order to clarify the requirements of section 351B of the Public Health Service Act, as added by section ____2, the Secretary shall amend such regulations not later than 1 year after the date of enactment of this title.

(2) PROCEDURE.—In amending regulations under paragraph (1), the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulations;

(B) provide a period of not more than 60 days for comments on the proposed regulations; and

(C) publish the final regulations not less than 30 days before the effective date of such regulations.

(c) PUBLIC MEETING.—In carrying out this title, including the amendment made by section ____2 and the amendments made by section ____3, the Secretary, not later than 90 days after the date of enactment of this title, shall have not less than 1 public meeting on the relevant regulatory policies relating to cellular and tissue therapeutic products described in section 351B(a) of the Public Health Service Act, as added by section ____2, including any changes to such policies necessary to encourage innovation and regulatory certainty with regard to the development of such products.