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

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 "Reliable and Effective Growth for Regenerative Health Options that Improve Wellness Act" or the "REGROW Act".

SEC. 2. REGENERATIVE THERAPEUTIC PRODUCTS.

(a) Current Pathways.—Nothing in this Act, or the amendments made by this Act, shall be applied or interpreted as restricting or otherwise modifying any pathway to market that is (on the day before the date enactment of this Act) provided under regulations promulgated by the Food and Drug Administration, including such pathways available under regulations promulgated under sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262, 264).

(b) Expedited Approval.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by transferring subsection (e) so that it appears before subsection (f); and

(2) by adding at the end the following:

"(g) Regenerative Therapeutic Products.—

"(1) In general.—For purposes of this section, the term 'drug' includes a regenerative therapeutic product.

"(2) Definition.—In this section, the term 'regenerative therapeutic product' means a cell therapy, gene therapy, gene-modified cell therapy, therapeutic tissue engineering product, human cell or tissue product, or combination product using any such therapy or product.".

(c) Accelerated Approval.—Section 506(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)(1)) is amended by adding at the end the following:

"(C) Regenerative therapeutic products.—In the case of a regenerative therapeutic product for which approval is sought under this subsection—

"(i) in considering whether to approve such product, the Secretary shall consider the unique and distinct attributes of the human cells, tissues, or cellular or tissue-based product;

"(ii) the Secretary shall include with the determination on whether to approve such product a written description of the full rationale for such determination; and

"(iii) the treatment of a serious condition for which the product is approved under this subsection may include a chronic, persistent, or recurring condition that affects day-to-day functioning without taking into account the availability or lack of alternative treatments.".

SEC. 3. DEVICES USED IN RECOVERY, PROCESSING, AND DELIVERY OF CELLULAR THERAPIES.

(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 device used in conjunction with a regenerative therapeutic product, as defined in section 506(g), the general function of the device used for the recovery, isolation, processing, or delivery of such product.".

(b) Clearance or Approval of Devices Used in Conjunction With Regenerative Therapeutic Products.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515A:
"SEC. 515B. CLASSIFICATION OF DEVICES USED IN CONJUNCTION WITH REGENERATIVE THERAPEUTIC PRODUCTS.
"(a) In General.—Clearance or approval under section 510(k) or 515 of a device that is used in conjunction with a regenerative therapeutic product (as defined in section 506(g)) for the recovery, isolation, processing, or delivery of such product shall be based on in vitro performance testing and not in vivo human clinical trials, as appropriate. If the Secretary determines in accordance with section 510(k) that a device described in subsection (a) is not substantially equivalent to a predicate device, the Secretary shall classify the device based on its general use for the recovery, isolation, processing, or delivery of the regenerative therapeutic product with which the device is used and sustaining the viability and functions of the cells or tissue in vivo. The Secretary shall not require that such a device 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 uses of the devices. 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) devices used in conjunction with regenerative therapy products, the agency center charged with premarket review of biological products shall have primary jurisdiction.".

SEC. 4. GUIDANCE; AMENDED REGULATIONS.
(a) Guidance.—Not later than 1 year after the date of enactment of this Act, 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 regenerative therapy products that are approved under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as amended by section 2), and devices used in the recovery, isolation, processing, or delivery of such products, as set forth in section 510(k)(3) of such Act (21 U.S.C. 360)(as amended by section 3) and section 515B of such Act (as added by section 3). 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.
(b) Amended Regulations.—
(1) In general.—If the Secretary determines that it is appropriate to amend the regulations under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) in order to clarify the amendments under section 2, the Secretary shall amend such regulations not later than 1 year after the date of enactment of this Act.
(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 Act, including the amendments made by this Act, the Secretary, not later than 90 days after the date of enactment of this Act, shall have not less than 1 public meeting on the relevant regulatory policies relating to regenerative therapy products, including any changes to such policies necessary to encourage innovation and regulatory certainty with regard to the development of regenerative therapy products.
(d) Report to Congress.—On an annual basis before March 1 of each calendar year, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives the number and type of applications for approval of regenerative therapy products, the number of such applications granted and the number of such applications denied, and a detailed description of the rationale for each determination with respect to granting or denying such an application during the previous calendar year.
(e) Regenerative Therapy Product.—In this section, the term "regenerative therapy product" has the meaning given such term in section 506(g) of the Federal Food, Drug, and Cosmetic Act, as amended by section 2.

SEC. 5. STANDARDS FOR REGENERATIVE MEDICINE AND ADVANCED THERAPIES.
Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following:
"SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE AND ADVANCED THERAPIES.
"(a) In General.—Not later than 1 year after the date of enactment, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards, through a transparent public process, that will help support product development, evaluation, and review, with respect to regenerative therapy products, through regulatory predictability, including with regard to manufacturing processes and controls for regenerative therapy products.
"(b) Activities.—
"(1) In general.—In carrying out this section, the Secretary shall continue to—
"(A) identity opportunities to help advance the development of regenerative therapy products;
"(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative therapy products through regulatory predictability; and
"(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.
"(2) Regulations and guidance.—Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a transparent public process, update such regulations and guidance as the Secretary determines appropriate.
"(c) Definition.—For purposes of this section, the term 'regenerative therapy product' has the meaning given such term in section 506(g).".