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114TH CONGRESS
2D SESSION

H. R. 4762

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 16, 2016

Mr. COFFMAN (for himself, Mr. TAKAI, and Mr. GRIFFITH) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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'' or the ''REGROW Act''.

SEC. 2. CELLULAR THERAPEUTICS.

(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 path-

way to market which is (as of the day immediately before the date of enactment of this Act) provided under regulations 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 adding after section 351A the following:

"SEC. 351B. APPROVAL FOR CELLULAR THERAPIES.

"(a) CONDITIONAL APPROVAL OF CELLULAR OR TISSUE THERAPEUTIC.—Not later than 1 year after the date of enactment of this section, the Secretary shall establish a program to conditionally approve a cellular therapeutic product if the sponsor of such product demonstrates preliminary clinical evidence of safety, and a reasonable expectation of effectiveness, without initiation of phase III investigations.

"(b) ADDITIONAL REQUIREMENTS FOR CONDITIONAL APPROVAL.—A conditionally approved product under subsection (a) shall, for a 5-year conditional use period, 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 all 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 nonhomologous use; or

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

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

''(5) Such cells or tissues are produced exclusively for a use that performs, or helps achieve or restore, the same, or similar, function in the recipient as in the donor.

''(6) Within 5 years of the safety and effectiveness determination described in this section, the sponsor of the conditionally approved new product prepares and submits an application for approval of a biological product under section 351(a), dem-

onstrating potency, purity, safety, and efficacy of the use. The Secretary may permit continued use of such product until the Secretary completes the review of the application and makes a determination. Upon a determination by the Secretary not to approve the application, use of the cellular therapeutic shall not be permitted.

''(7) During the conditional approval period, and before approval of an application under section 351(a), the sponsor shall prepare and submit annual reports and adverse event reports to the Secretary 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 the patients during the 5-year conditional use period.

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

''(c) INFORMED USE.—The individual administering a product approved under subsection (b) shall inform each individual who uses such product that the product has been conditionally approved based on studies in a limited

population, without proof of efficacy, and that the Secretary is requiring additional studies of the product.

''(d) 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.''.

SEC. 3. DEVICES USED IN RECOVERY, PROCESSING, AND DELIVERY OF CELLULAR 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 therapeutic 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 cellular therapeutic.''.

(b) CLEARANCE OR APPROVAL OF CELLULAR THERAPEUTICS.—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 THERAPEUTICS.

"Clearance or approval of a device that is a cellular therapeutic 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 used for cell therapy (as described in section 351B(a) of the Public Health Service Act), 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 Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may issue draft guidance on clarifying the requirements with respect to cellular therapeutics, as set forth in section 351B of the Public Health Service Act, as added by section 2, and devices used in processing or delivery of cellular therapeutics, 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 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 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 Act, shall have not less than 1 public meeting on the relevant regulatory policies relating to cell and tissue products, including any changes to such policies necessary to encourage innovation

and regulatory certainty with regard to the development of regenerative medicine products.

SEC. 5. REGENERATIVE MEDICINE STANDARDS.

The Secretary shall work with stakeholders, including regenerative product manufacturers, academic institutions, standards setting organizations, and the National Institute of Standards and Technology, to promote and facilitate an effort to develop, through a transparent public process, standards that will facilitate regulatory predictability regarding manufacturing processes and controls for regenerative medicine products.

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