

114TH CONGRESS  
2D SESSION

# S. 2689

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

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IN THE SENATE OF THE UNITED STATES

MARCH 16, 2016

Mr. KIRK (for himself, Mr. MANCHIN, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

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

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Reliable and Effective  
5 Growth for Regenerative Health Options that Improve  
6 Wellness” or the “REGROW Act”.

7 **SEC. 2. CELLULAR THERAPEUTICS.**

8 (a) CURRENT PATHWAYS.—Nothing in this Act, or  
9 the amendments made by this Act, shall be applied or in-  
10 terpreted as restricting or otherwise modifying any path-

1 way to market which is (as of the day immediately before  
2 the date of enactment of this Act) provided under regula-  
3 tions promulgated by the Food and Drug Administration,  
4 including pathways under sections 351 and 361 of the  
5 Public Health Service Act (42 U.S.C. 262 and 264).

6 (b) APPROVAL FOR THERAPIES.—Subpart 1 of part  
7 F of title III of the Public Health Service Act (42 U.S.C.  
8 262 et seq.) is amended by adding after section 351A the  
9 following:

10 **“SEC. 351B. APPROVAL FOR CELLULAR THERAPIES.**

11 “(a) CONDITIONAL APPROVAL OF CELLULAR OR TIS-  
12 SUE THERAPEUTIC.—Not later than 1 year after the date  
13 of enactment of this section, the Secretary shall establish  
14 a program to conditionally approve a cellular therapeutic  
15 product if the sponsor of such product demonstrates pre-  
16 liminary clinical evidence of safety, and a reasonable ex-  
17 pectation of effectiveness, without initiation of phase III  
18 investigations.

19 “(b) ADDITIONAL REQUIREMENTS FOR CONDI-  
20 TIONAL APPROVAL.—A conditionally approved product  
21 under subsection (a) shall, for a 5-year conditional use pe-  
22 riod, be manufactured, introduced into interstate com-  
23 merce, and used consistent with the regulations in effect  
24 at the time of such use, including good manufacturing

1 practices, without the approval of an application under  
2 section 351(a), if all of the following apply:

3           “(1) Such cells or tissues are adult human cells  
4 or tissues.

5           “(2) Such cells or tissues have been evaluated  
6 to examine immunogenicity and do not provoke a  
7 significant unintended immune response in the re-  
8 cipient.

9           “(3) Such cells or tissues are—

10           “(A) minimally manipulated for a non-  
11 homologous use; or

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

15           “(4) Such cells or tissues are produced for a  
16 specific indication.

17           “(5) Such cells or tissues are produced exclu-  
18 sively for a use that performs, or helps achieve or re-  
19 store, the same, or similar, function in the recipient  
20 as in the donor.

21           “(6) Within 5 years of the safety and effective-  
22 ness determination described in this section, the  
23 sponsor of the conditionally approved new product  
24 prepares and submits an application for approval of  
25 a biological product under section 351(a), dem-

1       onstrating potency, purity, safety, and efficacy of the  
2       use. The Secretary may permit continued use of  
3       such product until the Secretary completes the re-  
4       view of the application and makes a determination.  
5       Upon a determination by the Secretary not to ap-  
6       prove the application, use of the cellular therapeutic  
7       shall not be permitted.

8               “(7) During the conditional approval period,  
9       and before approval of an application under section  
10       351(a), the sponsor shall prepare and submit annual  
11       reports and adverse event reports to the Secretary  
12       containing all the information required for approved  
13       biological products.

14              “(8) The sponsor has submitted an application  
15       under section 505(i) of the Federal Food, Drug, and  
16       Cosmetic Act for the treatment of the patients dur-  
17       ing the 5-year conditional use period.

18              “(9) The sponsor has not previously received  
19       conditional approval for such product for the same  
20       indication.

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

1 population, without proof of efficacy, and that the Sec-  
2 retary is requiring additional studies of the product.

3 “(d) STEM CELL BANKING.—To be eligible to pro-  
4 vide cells for the uses described under subsection (b), pub-  
5 lic and private cord blood banks, tissue banks, and bone  
6 marrow repositories shall be in full compliance with good  
7 tissue practice requirements under part 1271 of title 21,  
8 Code of Federal Regulations (or successor regulations), as  
9 applicable.”.

10 **SEC. 3. DEVICES USED IN RECOVERY, PROCESSING, AND**  
11 **DELIVERY OF CELLULAR THERAPEUTICS.**

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

15 (1) in paragraph (1), by striking “, and” and  
16 inserting “;”;

17 (2) in paragraph (2), by striking the period and  
18 inserting “; and”; and

19 (3) by inserting after paragraph (2) the fol-  
20 lowing:

21 “(3) in the case of a cellular therapeutic de-  
22 scribed in section 351B(a) of the Public Health  
23 Service Act, the general function of the device used  
24 for the recovery, isolation, processing, or delivery of  
25 such cellular therapeutic.”.

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

5 **“SEC. 515B. CLASSIFICATION OF CELLULAR THERA-**  
6 **PEUTICS.**

7 “Clearance or approval of a device that is a cellular  
8 therapeutic described in section 351B(a) of the Public  
9 Health Service Act shall be based on in vitro performance  
10 testing and not in vivo human clinical trials, as appro-  
11 priate. The Secretary shall classify devices in accordance  
12 with section 513 used for cell therapy (as described in sec-  
13 tion 351B(a) of the Public Health Service Act), focusing  
14 on the general use of such devices for harvesting, delivery,  
15 or processing cells and sustaining the viability and func-  
16 tions of the cells in vivo. The classification regulation shall  
17 not require that such devices be cleared under section  
18 510(k) or approved under section 515 for use with only  
19 specific types of cells or for specific uses unless unique  
20 to the intended use of the device. If the Secretary deter-  
21 mines that no predicate exists, or that a device classified  
22 as class III is sufficiently low risk to justify a lower classi-  
23 fication, the Secretary shall apply the procedure outlined  
24 in section 513(f)(2) to permit the review and marketing  
25 of the device.”.

1 (c) COMBINATION PRODUCTS.—Section 503(g)(1) of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 353(g)(1)) is amended—

4 (1) in subparagraph (B), by striking “or”;

5 (2) in subparagraph (C), by striking the period  
6 and inserting “, or”; and

7 (3) by adding at the end the following:

8 “(D) cellular components, the agency center  
9 charged with premarket review of biological products  
10 shall have primary jurisdiction.”.

11 **SEC. 4. GUIDANCE; AMENDED REGULATIONS.**

12 (a) GUIDANCE.—Within 1 year of the date of enact-  
13 ment of this Act, the Secretary of Health and Human  
14 Services (referred to in this section as the “Secretary”)  
15 may issue draft guidance on clarifying the requirements  
16 with respect to cellular therapeutics, as set forth in section  
17 351B of the Public Health Service Act, as added by sec-  
18 tion 2, and devices used in processing or delivery of cel-  
19 lular therapeutics, as set forth in section 510(k)(3) of the  
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
21 360(k)(3)) and section 515B of such Act, as added by sec-  
22 tion 3(b). The Secretary shall issue final guidance not  
23 later than 180 days after the close of the comment period  
24 (including any extensions of such period) for the draft  
25 guidance. Such comment period may not exceed 60 days.

1 (b) AMENDED REGULATIONS.—

2 (1) IN GENERAL.—If the Secretary determines  
3 that it is appropriate to amend the regulations  
4 under title 21, Code of Federal Regulations, in order  
5 to clarify the requirements of section 351B of the  
6 Public Health Service Act, as added by section 2,  
7 the Secretary shall amend such regulations not later  
8 than 1 year after the date of enactment of this Act.

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

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

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

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

19 (c) PUBLIC MEETING.—In carrying out this Act, in-  
20 cluding the amendment made by section 2 and the amend-  
21 ments made by section 3, the Secretary, not later than  
22 90 days after the date of enactment of this Act, shall have  
23 not less than 1 public meeting on the relevant regulatory  
24 policies relating to cell and tissue products, including any  
25 changes to such policies necessary to encourage innovation



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

3 **SEC. 5. REGENERATIVE MEDICINE STANDARDS.**

4       The Secretary shall work with stakeholders, including  
5 regenerative product manufacturers, academic institu-  
6 tions, standards setting organizations, and the National  
7 Institute of Standards and Technology, to promote and  
8 facilitate an effort to develop, through a transparent pub-  
9 lic process, standards that will facilitate regulatory pre-  
10 dictability regarding manufacturing processes and controls  
11 for regenerative medicine products.

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