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(Original Signature of Member)

113TH CONGRESS  
2D SESSION

**H. R.**

To amend the Federal Food, Drug, and Cosmetic Act to authorize a 6-month extension of certain exclusivity periods in the case of approved drugs that are subsequently approved for a new indication to prevent, diagnose, or treat a rare disease or condition, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. BILIRAKIS introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to authorize a 6-month extension of certain exclusivity periods in the case of approved drugs that are subsequently approved for a new indication to prevent, diagnose, or treat a rare disease or condition, and for other purposes.

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 “Orphan Product Ex-  
5 tensions Now Accelerating Cures and Treatments Act of  
6 2014”.

1 **SEC. 2. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG**  
2 **APPROVED FOR A NEW INDICATION FOR A**  
3 **RARE DISEASE OR CONDITION.**

4 (a) IN GENERAL.—Chapter V of the Federal Food,  
5 Drug, and Cosmetic Act is amended by inserting after sec-  
6 tion 505E of such Act (21 U.S.C. 355f) the following:

7 **“SEC. 505F. EXTENSION OF EXCLUSIVITY PERIODS FOR A**  
8 **DRUG APPROVED FOR A NEW INDICATION**  
9 **FOR A RARE DISEASE OR CONDITION.**

10 “(a) DESIGNATION.—

11 “(1) IN GENERAL.—The Secretary shall des-  
12 ignate a drug as a drug approved for a new indica-  
13 tion to prevent, diagnose, or treat a rare disease or  
14 condition for purposes of granting the extensions  
15 under subsection (b) if—

16 “(A) prior to approval of an application or  
17 supplemental application for the new indication,  
18 the drug was approved or licensed for mar-  
19 keting under section 505(c) of this Act or sec-  
20 tion 351(a) of the Public Health Service Act,  
21 but was not so approved or licensed for the new  
22 indication;

23 “(B)(i) the sponsor of the approved or li-  
24 censed drug files an application or a supple-  
25 mental application for approval of the new indi-

1 cation for use of the drug to prevent, diagnose,  
2 or treat the rare disease or condition; and

3 “(ii) the Secretary approves the application  
4 or supplemental application; and

5 “(C) the application or supplemental appli-  
6 cation for the new indication contains the con-  
7 sent of the applicant to notice being given by  
8 the Secretary under paragraph (4) respecting  
9 the designation of the drug.

10 “(2) REVOCATION OF DESIGNATION.—

11 “(A) IN GENERAL.—Except as provided in  
12 subparagraph (B), a designation under this  
13 subsection shall not be revoked for any reason.

14 “(B) EXCEPTION.—The Secretary may re-  
15 voke a designation of a drug under paragraph  
16 (1) if the Secretary finds that the application or  
17 supplemental application resulting in such des-  
18 ignation contained an untrue statement of ma-  
19 terial fact.

20 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE  
21 OF PRODUCTION FOR SOLELY COMMERCIAL REA-  
22 SONS.—A designation of a drug under paragraph (1)  
23 shall be subject to the condition that the sponsor of  
24 the drug will notify the Secretary of any discontinu-  
25 ance of the production of the drug for solely com-

1       mercials reasons at least one year before such dis-  
2       continuance.

3               “(4) NOTICE TO PUBLIC.—Notice respecting  
4       the designation of a drug under paragraph (1) shall  
5       be made available to the public.

6               “(b) EXTENSION.—If the Secretary designates a  
7       drug as a drug approved for a new indication for a rare  
8       disease or condition, as described in subsection (a)(1)—

9               “(1)(A) the 4-, 5-, and seven and one-half year  
10       periods described in subsections (c)(3)(E)(ii) and  
11       (j)(5)(F)(ii) of section 505, the 3-year periods de-  
12       scribed in clauses (iii) and (iv) of subsection  
13       (c)(3)(E) and clauses (iii) and (iv) of subsection  
14       (j)(5)(F) of section 505, and the 7-year period de-  
15       scribed in section 527, as applicable, shall be ex-  
16       tended by 6 months; or

17               “(B) the 4- and 12-year periods described in  
18       subparagraphs (A) and (B) of section 351(k)(7) of  
19       the Public Health Service Act and the 7-year period  
20       described in section 527, as applicable, shall be ex-  
21       tended by 6 months; and

22               “(2) if, at the time a drug is designated under  
23       subsection (a)(1)—

24               “(A) the drug is the subject of a listed pat-  
25       ent for which a certification has been submitted

1 under subsection (b)(2)(A)(ii) or  
2 (j)(2)(A)(vii)(II) of section 505 or a listed pat-  
3 ent for which a certification has been submitted  
4 under subsections (b)(2)(A)(iii) or  
5 (j)(2)(A)(vii)(III) of section 505, the period  
6 during which an application may not be ap-  
7 proved under section 505(c)(3) or section  
8 505(j)(5)(B) shall be extended by a period of 6  
9 months after the date the patent expires (in-  
10 cluding any patent extensions); or

11 “(B) the drug is the subject of a listed  
12 patent for which a certification has been sub-  
13 mitted under subsection (b)(2)(A)(iv) or  
14 (j)(2)(A)(vii)(IV) of section 505, and in the pat-  
15 ent infringement litigation resulting from the  
16 certification the court determines that the pat-  
17 ent is valid and would be infringed, the period  
18 during which an application may not be ap-  
19 proved under section 505(c)(3) or section  
20 505(j)(5)(B) shall be extended by a period of 6  
21 months after the date the patent expires (in-  
22 cluding any patent extensions).

23 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-  
24 FECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-  
25 sion under subsection (b) of a period shall be in addition

1 to any extension of the periods under sections 505A and  
2 505E of this Act and section 351(m) of the Public Health  
3 Service Act, as applicable, with respect to the drug.

4 “(d) LIMITATIONS.—The extension described in sub-  
5 section (b) shall not apply if the drug designated under  
6 subsection (a)(1) has previously received an extension by  
7 operation of subsection (b).

8 “(e) REGULATIONS.—

9 “(1) IN GENERAL.—Not later than 2 years  
10 after the date of enactment of this section, the Sec-  
11 retary shall adopt final regulations implementing  
12 this section.

13 “(2) PROCEDURE.—In promulgating a regula-  
14 tion implementing this section, the Secretary shall—

15 “(A) issue a notice of proposed rulemaking  
16 that includes the proposed regulation;

17 “(B) provide a period of not less than 60  
18 days for comments on the proposed regulation;  
19 and

20 “(C) publish the final regulation not less  
21 than 30 days before the effective date of the  
22 regulation.

23 “(3) RESTRICTIONS.—Notwithstanding any  
24 other provision of law, the Secretary shall promul-  
25 gate regulations implementing this section only as

1 described in paragraph (2), except that the Sec-  
2 retary may issue interim guidance for sponsors seek-  
3 ing to submit an application or supplemental appli-  
4 cation described in subsection (a) prior to the pro-  
5 mulgation of such regulations.

6 “(4) DESIGNATION PRIOR TO REGULATIONS.—  
7 The Secretary shall designate drugs under sub-  
8 section (a) prior to the promulgation of regulations  
9 under this subsection, if such drugs meet the criteria  
10 described in subsection (a).

11 “(f) DEFINITION.—In this section, the term ‘rare dis-  
12 ease or condition’ has the meaning given to such term in  
13 section 526(a)(2).”.

14 (b) APPLICATION.—Section 505F of the Federal  
15 Food, Drug, and Cosmetic Act, as added by subsection  
16 (a), applies only with respect to a drug for which an appli-  
17 cation or supplemental application described in subsection  
18 (a)(1)(B)(i) of such section 505F is first approved under  
19 section 505(c) of such Act (21 U.S.C. 355(c)) or section  
20 351(a) of the Public Health Service Act (42 U.S.C.  
21 262(a)) on or after the date of the enactment of this Act.

22 (c) CONFORMING AMENDMENTS.—

23 (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR  
24 DRUGS.—Section 505A of the Federal Food, Drug,  
25 and Cosmetic Act (21 U.S.C. 355a) is amended—

1 (A) in subsection (b), by adding at the end  
2 the following:

3 “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
4 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
5 EASE OR CONDITION.—Notwithstanding the ref-  
6 erences in subsection (b)(1) to the lengths of the ex-  
7 clusivity periods after application of pediatric exclu-  
8 sivity, the 6-month extensions described in sub-  
9 section (b)(1) shall be in addition to any extensions  
10 under section 505F.”; and

11 (B) in subsection (c), by adding at the end  
12 the following:

13 “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
14 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
15 EASE OR CONDITION.—Notwithstanding the ref-  
16 erences in subsection (c)(1) to the lengths of the ex-  
17 clusivity periods after application of pediatric exclu-  
18 sivity, the 6-month extensions described in sub-  
19 section (c)(1) shall be in addition to any extensions  
20 under section 505F.”.

21 (2) RELATION TO EXCLUSIVITY FOR NEW  
22 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT  
23 ARE DRUGS.—Subsection (b) of section 505E of the  
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25 355f) is amended—

1 (A) by amending the subsection heading to  
2 read as follows: “RELATION TO PEDIATRIC EX-  
3 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-  
4 PROVED FOR A NEW INDICATION FOR A RARE  
5 DISEASE OR CONDITION”; and

6 (B) by striking “any extension of the pe-  
7 riod under section 505A” and inserting “any  
8 extension of the periods under sections 505A or  
9 505F”.

10 (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR  
11 BIOLOGICAL PRODUCTS.—Section 351(m) of the  
12 Public Health Service Act (42 U.S.C. 262(m)) is  
13 amended by adding at the end the following:

14 “(5) RELATION TO EXCLUSIVITY FOR A BIO-  
15 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-  
16 TION FOR A RARE DISEASE OR CONDITION.—Not-  
17 withstanding the references in paragraphs (2)(A),  
18 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-  
19 clusivity periods after application of pediatric exclu-  
20 sivity, the 6-month extensions described in such  
21 paragraphs shall be in addition to any extensions  
22 under section 505F.”.