

112TH CONGRESS  
1ST SESSION

# S. 1734

To provide incentives for the development of qualified infectious disease products.

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IN THE SENATE OF THE UNITED STATES

OCTOBER 19, 2011

Mr. BLUMENTHAL (for himself, Mr. CORKER, Mr. BENNET, Mr. HATCH, Mr. CASEY, Mr. ALEXANDER, and Mr. COONS) 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 provide incentives for the development of qualified infectious disease products.

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 “Generating Antibiotic  
5 Incentives Now Act of 2011”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Extension of exclusivity period for drugs.

Sec. 4. Additional extension of exclusivity period for qualified infectious disease products for which a companion diagnostic test is cleared or approved.

Sec. 5. Priority review.

Sec. 6. Fast track product.

Sec. 7. Study on incentives for qualified infectious disease biological products.

Sec. 8. Clinical trials.

1 **SEC. 3. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

2 (a) IN GENERAL.—The Federal Food, Drug, and  
3 Cosmetic Act is amended by inserting after section 505D  
4 (21 U.S.C. 355e) the following:

5 **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW**  
6 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

7 “(a) EXTENSION.—If, prior to approval of a drug  
8 pursuant to an application submitted under section  
9 505(b), the Secretary determines that the drug is a quali-  
10 fied infectious disease product, then the four- and five-  
11 year periods described in subsections (c)(3)(E)(ii) and  
12 (j)(5)(F)(ii) of section 505, the three-year periods de-  
13 scribed in clauses (iii) and (iv) of subsection (c)(3)(E) and  
14 clauses (iii) and (iv) of subsection (j)(5)(F) of section 505,  
15 or the seven-year period described in section 527, as appli-  
16 cable, shall be extended by five years.

17 “(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any  
18 extension under subsection (a) of a period shall be in addi-  
19 tion to any extension of the period under section 505A  
20 with respect to the drug.

21 “(c) LIMITATIONS.—Subsection (a) does not apply to  
22 the approval of—

1           “(1) a supplement to an application under sec-  
2           tion 505(b) for any qualified infectious disease prod-  
3           uct for which an extension described in subsection  
4           (a) is in effect or has expired; or

5           “(2) a subsequent application filed by the same  
6           sponsor or manufacturer of a qualified infectious  
7           disease product described in paragraph (1) (or a li-  
8           censor, predecessor in interest, or other related enti-  
9           ty) for—

10           “(A) a change (not including a modifica-  
11           tion to the structure of the qualified infectious  
12           disease product) that results in a new indica-  
13           tion, route of administration, dosing schedule,  
14           dosage form, delivery system, delivery device, or  
15           strength; or

16           “(B) a modification to the structure of the  
17           qualified infectious disease product that does  
18           not result in a change in safety or effectiveness.

19           “(d) DETERMINATION.—The manufacturer or spon-  
20           sor of a drug may request the Secretary to designate a  
21           drug as a qualified infectious disease product. Such a re-  
22           quest for designation shall be made at least 45 days before  
23           the submission of an application under section 505(b) for  
24           such drug. The Secretary shall, not later than 30 days

1 after the submission of such request, determine whether  
2 the drug is a qualified infectious disease product.

3 “(e) REGULATIONS.—The Secretary shall promulgate  
4 regulations for carrying out this section. The Secretary  
5 shall promulgate the initial regulations for carrying out  
6 this section not later than 12 months after the date of  
7 the enactment of this section.

8 “(f) DEFINITIONS.—In this section:

9 “(1) QUALIFIED INFECTIOUS DISEASE PROD-  
10 UCT.—The term ‘qualified infectious disease prod-  
11 uct’ means an antibiotic drug for treating, detecting,  
12 preventing, or identifying a qualifying pathogen.

13 “(2) QUALIFYING PATHOGEN.—The term  
14 ‘qualifying pathogen’ means—

15 “(A) resistant gram positive pathogens, in-  
16 cluding methicillin-resistant *Staphylococcus*  
17 *aureus* (MRSA), vancomycin-resistant *Staphy-*  
18 *lococcus aureus* (VISA), and vancomycin-resist-  
19 ant enterococcus (VRE);

20 “(B) multi-drug resistant gram negative  
21 bacteria, including *Acinetobacter*, *Klebsiella*,  
22 *Pseudomonas*, and *E. coli* species;

23 “(C) multi-drug resistant tuberculosis; or

1           “(D) any other infectious pathogen identi-  
2           fied for purposes of this section by the Sec-  
3           retary.”.

4           (b) APPLICATION.—Section 505E of the Federal  
5 Food, Drug, and Cosmetic Act, as added by subsection  
6 (a), applies only with respect to a drug that is first ap-  
7 proved under section 505(c) of such Act (21 U.S.C.  
8 355(c)) on or after the date of the enactment of this Act.

9   **SEC. 4. ADDITIONAL EXTENSION OF EXCLUSIVITY PERIOD**  
10                           **FOR QUALIFIED INFECTIOUS DISEASE PROD-**  
11                           **UCTS FOR WHICH A COMPANION DIAGNOSTIC**  
12                           **TEST IS CLEARED OR APPROVED.**

13           The Federal Food, Drug, and Cosmetic Act (21  
14 U.S.C. 301 et seq.), as amended by section 3, is further  
15 amended by inserting after section 505E the following:

16   **“SEC. 505E-1. ADDITIONAL EXTENSION OF EXCLUSIVITY**  
17                           **FOR QUALIFIED INFECTIOUS DISEASE PROD-**  
18                           **UCTS FOR WHICH A COMPANION DIAGNOSTIC**  
19                           **TEST IS CLEARED OR APPROVED.**

20           “(a) IN GENERAL.—If the sponsor or manufacturer  
21 of a qualified infectious disease product identifies in ac-  
22 cordance with subsection (b) a companion diagnostic test  
23 described in subsection (c), any period extended under sec-  
24 tion 505E(a) with respect to such product shall be further  
25 extended by 6 months.

1       “(b) IDENTIFICATION REQUIREMENTS.—For pur-  
2 poses of subsection (a), the identification of a companion  
3 diagnostic test shall—

4               “(1) be made in such manner as the Secretary  
5 may require; and

6               “(2) occur before the expiration of the period to  
7 be extended under subsection (a), not counting any  
8 extension to such period under section 505E(a) or  
9 505A.

10       “(c) COMPANION DIAGNOSTIC TEST.—For purposes  
11 of subsection (a), a device is a companion diagnostic test  
12 with respect to a qualified infectious disease product if  
13 each of the following is met:

14               “(1) The device is determined by the Secretary  
15 under subsection (f) to be a test for diagnosis of a  
16 qualifying pathogen.

17               “(2) The qualified infectious disease product  
18 has been determined under section 505E(d) to be for  
19 treating, detecting, preventing, or identifying such  
20 qualifying pathogen.

21               “(3) The device is cleared under section 510(k)  
22 or approved under section 515.

23               “(4) The sponsor or manufacturer, as applica-  
24 ble, of the qualified infectious disease product has

1 the exclusive rights to submit an identification under  
2 subsection (a) with respect to the device.

3 “(d) RELATION TO PEDIATRIC EXCLUSIVITY.—Any  
4 extension under subsection (a) of a period with respect  
5 to a qualified infectious disease product shall be in addi-  
6 tion to any extension of the period under section 505A  
7 of this Act with respect to the product.

8 “(e) LIMITATIONS.—After the extension of any pe-  
9 riod under subsection (a) with respect to a qualified infec-  
10 tious disease product pursuant to the identification of a  
11 device as a companion diagnostic test, subsection (a) does  
12 not authorize—

13 “(1) any subsequent extension with respect to  
14 such product; or

15 “(2) any extension with respect to any other  
16 product pursuant to identification of such device.

17 “(f) DETERMINATION.—The sponsor or manufac-  
18 turer of a drug may request the Secretary to determine  
19 that a device is a test for diagnosis of a qualifying patho-  
20 gen. Such a request shall be made at least 45 days before  
21 the submission of a notification under section 510(k) or  
22 an application under section 515 for such device. The Sec-  
23 retary shall, not later than 30 days after the submission  
24 of such request, determine whether the device is a test  
25 for diagnosis of a qualifying pathogen.

1 “(g) DEFINITIONS.—In this section:

2 “(1) The term ‘qualified infectious disease  
3 product’ means a drug that is determined to be a  
4 qualified infectious disease product under section  
5 505E.

6 “(2) The term ‘qualifying pathogen’ has the  
7 meaning given to such term in section 505E.”.

8 **SEC. 5. PRIORITY REVIEW.**

9 (a) AMENDMENT.—Chapter V of the Federal Food,  
10 Drug, and Cosmetic Act is amended by inserting after sec-  
11 tion 524 (21 U.S.C. 360n) the following:

12 **“SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS**  
13 **DISEASE PRODUCTS.**

14 “(a) IN GENERAL.—If the Secretary makes a deter-  
15 mination under section 505E(c) that a drug is a qualified  
16 infectious disease product, then the Secretary shall give  
17 priority review to any application submitted for approval  
18 for such drug under section 505(b).

19 “(b) DEFINITION.—In this section, the term ‘priority  
20 review’, with respect to an application described in sub-  
21 section (a), means review and action by the Secretary on  
22 such application not later than 6 months after receipt by  
23 the Secretary of such application.”.

24 (b) APPLICATION.—Section 524A of the Federal  
25 Food, Drug, and Cosmetic Act, as added by subsection



1 (a), applies only with respect to an application that is sub-  
2 mitted under section 505(b) (21 U.S.C. 355(b)) on or  
3 after the date of the enactment of this Act.

4 **SEC. 6. FAST TRACK PRODUCT.**

5 Paragraph (1) of section 506(a) of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 356(a)) is amended  
7 by inserting after “if it is intended for the treatment of  
8 a serious or life-threatening condition and it demonstrates  
9 the potential to address unmet medical needs for such a  
10 condition” the following: “or if the Secretary determines  
11 under section 505E that the drug is a qualified infectious  
12 disease product”.

13 **SEC. 7. STUDY ON INCENTIVES FOR QUALIFIED INFEC-**  
14 **TIOUS DISEASE BIOLOGICAL PRODUCTS.**

15 (a) IN GENERAL.—The Comptroller General of the  
16 United States shall—

17 (1) conduct a study on the need for incentives  
18 to encourage the research, development, and mar-  
19 keting of qualified infectious disease biological prod-  
20 ucts; and

21 (2) not later than 1 year after the date of the  
22 enactment of this Act, submit a report to the Con-  
23 gress on the results of such study, including any rec-  
24 ommendations of the Comptroller General on appro-  
25 priate incentives for addressing such need.

1 (b) DEFINITIONS.—In this section:

2 (1) The term “biological product” has the  
3 meaning given to such term in section 351 of the  
4 Public Health Service Act (42 U.S.C. 262).

5 (2) The term “qualified infectious disease bio-  
6 logical product” means a biological product for  
7 treating, detecting, preventing, or identifying a  
8 qualifying pathogen.

9 (3) The term “qualifying pathogen” has the  
10 meaning given to such term in section 505E of the  
11 Federal Food, Drug, and Cosmetic Act, as added by  
12 section 3 of this Act.

13 **SEC. 8. CLINICAL TRIALS.**

14 (a) REVIEW AND REVISION OF GUIDELINES.—

15 (1) IN GENERAL.—Not later than 1 year after  
16 the date of the enactment of this Act, and not later  
17 than 4 years thereafter, the Secretary shall—

18 (A) review the guidelines of the Food and  
19 Drug Administration for the conduct of clinical  
20 trials with respect to antibiotic drugs; and

21 (B) as appropriate, revise such guidelines  
22 to reflect developments in scientific and medical  
23 information and technology and to ensure clar-  
24 ity regarding the procedures and requirements  
25 for approval of an antibiotic drug under chapter

1 V of the Federal Food, Drug, and Cosmetic Act  
2 (21 U.S.C. 351 et seq.).

3 (2) ISSUES FOR REVIEW.—At a minimum, the  
4 review under paragraph (1) shall address the appro-  
5 priate animal models of infection, in vitro tech-  
6 niques, valid micro-biological surrogate markers, the  
7 use of non-inferiority versus superiority trials, and  
8 appropriate delta values for non-inferiority trials.

9 (3) RULE OF CONSTRUCTION.—Except to the  
10 extent to which the Secretary of Health and Human  
11 Services makes revisions under paragraph (1)(B),  
12 nothing in this section shall be construed to repeal  
13 or otherwise affect the guidelines of the Food and  
14 Drug Administration.

15 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

16 (1) REQUEST.—The sponsor of a drug intended  
17 to be used to treat, detect, prevent, or identify a  
18 qualifying pathogen may request that the Secretary  
19 provide written recommendations for nonclinical and  
20 clinical investigations which may be conducted with  
21 the drug before it may be approved for such use  
22 under section 505 of the Federal Food, Drug, and  
23 Cosmetic Act (21 U.S.C. 355).

24 (2) RECOMMENDATIONS.—If the Secretary has  
25 reason to believe that a drug for which a request is

1       made under this subsection is a qualified infections  
2       disease product, the Secretary shall provide the per-  
3       son making the request written recommendations for  
4       the nonclinical and clinical investigations which the  
5       Secretary believes, on the basis of information avail-  
6       able to the Secretary at the time of the request,  
7       would be necessary for approval under section 505  
8       of the Federal Food, Drug, and Cosmetic Act (21  
9       U.S.C. 355) of such drug for the use described in  
10      paragraph (1).

11      (c) DEFINITIONS.—In this section:

12           (1) The term “drug” has the meaning given to  
13           such term in section 201 of the Federal Food, Drug,  
14           and Cosmetic Act (21 U.S.C. 321).

15           (2) The term “qualifying pathogen” has the  
16           meaning given to such term in section 505E of the  
17           Federal Food, Drug, and Cosmetic Act, as added by  
18           section 3 of this Act.

19           (3) The term “Secretary” means the Secretary  
20           of Health and Human Services, acting through the  
21           Commissioner of Food and Drugs.

○