

112TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

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 “_____ Act of
5 _____”.

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 products.

Sec. 8. Clinical trials.

Sec. 9. Regulatory certainty and predictability.

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 the Secretary approves an ap-
8 plication pursuant to section 505 for a drug that has been
9 designated as a qualified infectious disease product under
10 subsection (d), the **[4- and] 5-year period[s]** described
11 in subsection**[s] [(c)(3)(E)(ii) and] (j)(5)(F)(ii)** of sec-
12 tion 505, the 3-year periods described in clauses (iii) and
13 (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of
14 subsection (j)(5)(F) of section 505, or the 7-year period
15 described in section 527, as applicable, shall be extended
16 by 5 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;

5 “(2) a subsequent application filed with respect
6 to a product approved under section 505 for—

7 “(A) a change that results in a new indica-
8 tion, route of administration, dosing schedule,
9 dosage form, delivery system, delivery device, or
10 strength; or

11 “(B) a modification to the moiety of the
12 qualified infectious disease product that does
13 not result in a change in safety or effectiveness;
14 or

15 “(3) a product that is not indicated for the use
16 for which it received a designation under subsection
17 (d).

18 “(d) DESIGNATION.—

19 “(1) IN GENERAL.—The manufacturer or spon-
20 sor of a drug may request the Secretary to designate
21 a drug as a qualified infectious disease product at
22 any time before the submission of an application
23 under section 505(b) for such drug.

24 “(2) LIMITATION.—A designation under this
25 subsection shall not be withdrawn for any reason, in-

1 including modifications to the list of qualifying patho-
2 gens under subsection (f)(2)(C).

3 “(e) REGULATIONS.—

4 “(1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of the **[insert short title]**, the
6 Secretary shall adopt final regulations implementing
7 this section.

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

10 “(A) issue a notice of proposed rulemaking
11 that includes a copy of the proposed regulation;

12 “(B) provide a period of not less than 60
13 days for comments on the proposed regulation;
14 and

15 “(C) publish the final regulation not less
16 than 30 days before the effective date of the
17 regulation.

18 “(3) RESTRICTIONS.—Notwithstanding any
19 other provision of law, the Secretary shall promul-
20 gate regulations implementing this section only as
21 described in paragraph (2), except that the Sec-
22 retary may issue interim guidance for sponsors seek-
23 ing designation under subsection (d) prior to the
24 promulgation of such regulations.

25 “(f) QUALIFYING PATHOGEN.—

1 “(1) DEFINITION.—In this section, the term
2 ‘qualifying pathogen’ means a pathogen identified
3 and listed by the Secretary under paragraph (2) that
4 has the potential to pose a serious threat to public
5 health, such as—

6 “(A) resistant gram positive pathogens, in-
7 cluding methicillin-resistant *Staphylococcus*
8 aureus, vancomycin-resistant *Staphylococcus*
9 aureus, and vancomycin-resistant enterococcus;

10 “(B) multi-drug resistant gram negative
11 bacteria, including *Acinetobacter*, *Klebsiella*,
12 *Pseudomonas*, and *E. coli* species;

13 “(C) multi-drug resistant tuberculosis; and

14 “(D) *Clostridium difficile*.

15 “(2) LIST OF QUALIFYING PATHOGENS.—

16 “(A) IN GENERAL.—The Secretary shall
17 establish and maintain a list of qualifying
18 pathogens.

19 “(B) CONSIDERATIONS.—In establishing
20 and maintaining the list of pathogens described
21 under this section the Secretary shall—

22 “(i) consider—

23 “(I) the impact on the public
24 health due to drug-resistant orga-
25 nisms in humans;

1 “(II) the rate of growth of drug-
2 resistant organisms in humans;

3 “(III) the increase in resistance
4 rates in humans; and

5 “(IV) the morbidity and mor-
6 tality in humans; and

7 “(ii) consult with experts in infectious
8 diseases, including the Centers for Disease
9 Control and Prevention, the Food and
10 Drug Administration, medical profes-
11 sionals, and the clinical research commu-
12 nity.

13 “(C) REVIEW.—Every 5 years, or more
14 often as needed, the Secretary shall review, pro-
15 vide modifications to, and publish the list of
16 qualifying pathogens under subparagraph (A)
17 and shall by regulation revise the list as nec-
18 essary, in accordance with subsection (e).

19 “(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—
20 The term ‘qualified infectious disease product’ means an
21 antibacterial or antifungal drug for human use intended
22 to treat serious or life-threatening infections, including
23 those caused by—

1 “(1) an antibacterial or antifungal resistant
2 pathogen, including novel or emerging infectious
3 pathogens; or

4 “(2) qualifying pathogens listed by the Sec-
5 retary under subsection (f).”.

6 (b) APPLICATION.—Section 505E of the Federal
7 Food, Drug, and Cosmetic Act, as added by subsection
8 (a), applies only with respect to a drug that is first ap-
9 proved under section 505(c) of such Act (21 U.S.C.
10 355(c)) on or after the date of the enactment of this Act.

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

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

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

22 “(a) IN GENERAL.—If the sponsor or manufacturer
23 of a qualified infectious disease product identifies in ac-
24 cordance with subsection (b) a companion diagnostic test
25 described in subsection (c), any period extended under sec-

1 tion 505E(a) with respect to such product shall be further
2 extended by 6 months.

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

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

8 “(2) occur before the expiration of the period to
9 be extended under subsection (a), not counting any
10 extension to such period under section 505E(a) or
11 505A.

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

16 “(1) The device is determined by the Secretary
17 to be a test for diagnosis of an infection described
18 in section 505E(g).

19 “(2) The qualified infectious disease product
20 has been designated under section 505E(d) to be for
21 treating such qualifying pathogen.

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

24 “(d) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
25 extension under subsection (a) of a period with respect

1 to a qualified infectious disease product shall be in addi-
2 tion to any extension of the period under section 505A
3 of this Act with respect to the product.

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

9 “(1) any subsequent extension with respect to
10 such product; or

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

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

22 “(g) DEFINITIONS.—In this section:

23 “(1) The term ‘qualified infectious disease
24 product’ means a drug that is determined to be a

1 qualified infectious disease product under section
2 505E.

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

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

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

9 **“SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS**
10 **DISEASE PRODUCTS.**

11 “If the Secretary designates a drug under section
12 505E(d) as a qualified infectious disease product, then the
13 Secretary shall give priority review to any application sub-
14 mitted for approval for such drug under section 505(b).”.

15 (b) APPLICATION.—Section 524A of the Federal
16 Food, Drug, and Cosmetic Act, as added by subsection
17 (a), applies only with respect to an application that is sub-
18 mitted under section 505(b) (21 U.S.C. 355(b)) on or
19 after the date of the enactment of this Act.

20 **SEC. 6. FAST TRACK PRODUCT.**

21 Section 506(a)(1) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 356(a)(1)) is amended by insert-
23 ing “or if the Secretary designates the drug as a qualified
24 infectious disease product under section 505E(d)” after
25 “such a condition”.

1 **SEC. 7. GAO STUDY.**

2 (a) IN GENERAL.—The Comptroller General of the
3 United States shall—

4 (1) conduct a study—

5 (A) on the need for incentives to encourage
6 the research, development, and marketing of
7 qualified infectious disease biological products
8 and antifungal products; and

9 (B) consistent with trade and confiden-
10 tiality data protections, assessing, for all anti-
11 bacterial and antifungal drugs, including bio-
12 logical products, the average or aggregate—

13 (i) costs of all clinical trials for each
14 phase;

15 (ii) percentage of success or failure at
16 each phase of clinical trials; and

17 (iii) public versus private funding lev-
18 els of the trials for each phase; and

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

24 (b) CONTENTS.—The part of the study described in
25 subsection (a)(1)(A) shall include—

1 (1) an assessment of any underlying regulatory
2 issues related to qualified infectious disease prod-
3 ucts, including qualified infectious disease biological
4 products;

5 (2) an assessment of the management by the
6 Food and Drug Administration of the review of
7 qualified infectious disease products, including quali-
8 fied infectious disease biological products and the
9 regulatory certainty of related regulatory pathways
10 for such products;

11 (3) a description of any regulatory impediments
12 to the clinical development of new qualified infec-
13 tious disease products, including qualified infectious
14 disease biological products, and the efforts of the
15 Food and Drug Administration to address such im-
16 pediments; and

17 (4) recommendations with respect to—

18 (A) improving the review and predictability
19 of regulatory pathways for such products; and

20 (B) overcoming any regulatory impedi-
21 ments identified in paragraph (3).

22 (c) DEFINITIONS.—In this section:

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

1 (2) The term “qualified infectious disease bio-
2 logical product” means a biological product intended
3 to treat a serious or life-threatening infection de-
4 scribed in section 505E(g).

5 (3) The term “qualified infectious disease prod-
6 uct” has the meaning given such term in section
7 505E(g) of the Federal Food, Drug, and Cosmetic
8 Act, as added by section 3.

9 **SEC. 8. CLINICAL TRIALS.**

10 (a) REVIEW AND REVISION OF GUIDELINES.—

11 (1) IN GENERAL.—The Secretary shall review
12 and, as appropriate, revise not fewer than 3 guid-
13 ances per year, which shall include—

14 (A) reviewing the guidelines of the Food
15 and Drug Administration for the conduct of
16 clinical trials with respect to antibiotic drugs;
17 and

18 (B) as appropriate, revising such guide-
19 lines to reflect developments in scientific and
20 medical information and technology and to en-
21 sure clarity regarding the procedures and re-
22 quirements for approval of an antibiotic drug
23 under chapter V of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 351 et seq.).

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

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

13 (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

14 (1) REQUEST.—The sponsor of a drug intended
15 to be designated as a qualified infectious disease
16 product may request that the Secretary provide writ-
17 ten recommendations for nonclinical and clinical in-
18 vestigations which the Secretary believes may be
19 necessary to be conducted with the drug before such
20 drug may be approved under section 505 of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)
22 for use in treating, detecting, preventing, or identi-
23 fying a qualifying pathogen.

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 infectious
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) GAO STUDY.—Not later than 3 years after the
12 date of enactment of this Act, the Comptroller General
13 of the United States shall submit to Congress a report—

14 (1) regarding the review and revision of the
15 clinical trial guidelines required under subsection (a)
16 and the impact such review and revision has had on
17 the review and approval of qualified infectious dis-
18 ease products;

19 (2) assessing the management of reviewers of
20 such products by the Food and Drug Administration
21 and the predictability of related regulatory pathways
22 and review;

23 (3) identifying any outstanding regulatory im-
24 pediments to the clinical development of qualified in-
25 fectious disease products;

1 (4) reporting on the progress the Food and
2 Drug Administration has made in addressing the im-
3 pediments identified under paragraph (3); and

4 (5) containing recommendations regarding how
5 to improve the review of, and regulatory pathway
6 for, such products.

7 (d) DEFINITIONS.—In this section:

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

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

15 (3) The term “Secretary” means the Secretary
16 of Health and Human Services, acting through the
17 Commissioner of Food and Drugs.

18 **SEC. 9. REGULATORY CERTAINTY AND PREDICTABILITY.**

19 (a) INITIAL STRATEGY AND IMPLEMENTATION
20 PLAN.—Not later than 1 year after the date of enactment
21 of this Act, the Secretary of Health and Human Services
22 (referred to in this section as the “Secretary”) shall sub-
23 mit to Congress a strategy and implementation plan with
24 respect to the requirements of this Act. The strategy and
25 implementation plan shall include—

1 (1) a description of the regulatory challenges to
2 clinical development, approval, and licensure of
3 qualified infectious disease products;

4 (2) the regulatory and scientific priorities of the
5 Secretary with respect to such challenges; and

6 (3) the steps the Secretary will take to ensure
7 regulatory certainty and predictability with respect
8 to qualified infectious disease products, including
9 steps the Secretary will take to ensure managers and
10 reviewers are familiar with related regulatory path-
11 ways, requirements of the Food and Drug Adminis-
12 tration, guidance related to such products, and ap-
13 plying such requirements consistently.

14 (b) **SUBSEQUENT REPORT.**—Not later than 3 years
15 after the date of enactment of this Act, the Secretary shall
16 submit to Congress a report on—

17 (1) the progress made toward the priorities
18 identified under subsection (a)(2);

19 (2) the number of qualified infectious disease
20 products that have been submitted for approval or li-
21 censure on or after the date of enactment of this
22 Act;

23 (3) a list of qualified infectious disease products
24 with information on the types of exclusivity granted
25 for each product, consistent with the information

1 published under section 505(j)(7)(A)(iii) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(j)(7)(A)(iii));

4 (4) the number of such qualified infectious dis-
5 ease products and that have been approved or li-
6 censed on or after the date of enactment of this Act;
7 and

8 (5) the number of calendar days it took for the
9 approval or licensure of the qualified infectious dis-
10 ease products approved or licensed on or after the
11 date of enactment of this Act.