112TH CONGRESS
1ST SESSION

S. 1734

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

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

A BILL

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

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 “Generating Antibiotic Incentives Now Act of 2011”.

SEC. 2. TABLE OF CONTENTS.

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.

SEC. 3. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.

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

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

“(a) Extension.—If, prior to approval of a drug pursuant to an application submitted under section 505(b), the Secretary determines that the drug is a qualified infectious disease product, then the four- and five-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the three-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the seven-year period described in section 527, as applicable, shall be extended by five years.

“(b) Relation to Pediatric Exclusivity.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

“(c) Limitations.—Subsection (a) does not apply to the approval of—
“(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired; or

“(2) a subsequent application filed by the same sponsor or manufacturer of a qualified infectious disease product described in paragraph (1) (or a licensor, predecessor in interest, or other related entity) for—

“(A) a change (not including a modification to the structure of the qualified infectious disease product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

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

“(d) DETERMINATION.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product. Such a request for designation shall be made at least 45 days before the submission of an application under section 505(b) for such drug. The Secretary shall, not later than 30 days
• after the submission of such request, determine whether
the drug is a qualified infectious disease product.

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

“(f) DEFINITIONS.—In this section:

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

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

“(A) resistant gram positive pathogens, in-
cluding methicillin-resistant Staphylococcus
aureus (MRSA), vancomycin-resistant Staphy-
lococcus aureus (VRSA), and vancomycin-resist-
ant enterococcus (VRE);

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

“(C) multi-drug resistant tuberculosis; or
“(D) any other infectious pathogen identified for purposes of this section by the Secretary.”.

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

SEC. 4. ADDITIONAL EXTENSION OF EXCLUSIVITY PERIOD FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS FOR WHICH A COMPANION DIAGNOSTIC TEST IS CLEARED OR APPROVED.

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

“SEC. 505E–1. ADDITIONAL EXTENSION OF EXCLUSIVITY FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS FOR WHICH A COMPANION DIAGNOSTIC TEST IS CLEARED OR APPROVED.

“(a) IN GENERAL.—If the sponsor or manufacturer of a qualified infectious disease product identifies in accordance with subsection (b) a companion diagnostic test described in subsection (c), any period extended under section 505E(a) with respect to such product shall be further extended by 6 months.
“(b) IDENTIFICATION REQUIREMENTS.—For purposes of subsection (a), the identification of a companion diagnostic test shall—

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

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

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

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

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

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

“(4) The sponsor or manufacturer, as applicable, of the qualified infectious disease product has
the exclusive rights to submit an identification under subsection (a) with respect to the device.

“(d) Relation to Pediatric Exclusivity.—Any extension under subsection (a) of a period with respect to a qualified infectious disease product shall be in addition to any extension of the period under section 505A of this Act with respect to the product.

“(e) Limitations.—After the extension of any period under subsection (a) with respect to a qualified infectious disease product pursuant to the identification of a device as a companion diagnostic test, subsection (a) does not authorize—

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

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

“(f) Determination.—The sponsor or manufacturer of a drug may request the Secretary to determine that a device is a test for diagnosis of a qualifying pathogen. Such a request shall be made at least 45 days before the submission of a notification under section 510(k) or an application under section 515 for such device. The Secretary shall, not later than 30 days after the submission of such request, determine whether the device is a test for diagnosis of a qualifying pathogen.
“(g) DEFINITIONS.—In this section:

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

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

SEC. 5. PRIORITY REVIEW.

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

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

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

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

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

SEC. 6. FAST TRACK PRODUCT.

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

SEC. 7. STUDY ON INCENTIVES FOR QUALIFIED INFECTIOUS DISEASE BIOLOGICAL PRODUCTS.

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

(1) conduct a study on the need for incentives to encourage the research, development, and marketing of qualified infectious disease biological products; and

(2) not later than 1 year after the date of the enactment of this Act, submit a report to the Congress on the results of such study, including any recommendations of the Comptroller General on appropriate incentives for addressing such need.
(b) Definitions.—In this section:

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

(2) The term “qualified infectious disease biological product” means a biological product for treating, detecting, preventing, or identifying a qualifying pathogen.

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

SEC. 8. CLINICAL TRIALS.

(a) Review and Revision of Guidelines.—

(1) In general.—Not later than 1 year after the date of the enactment of this Act, and not later than 4 years thereafter, the Secretary shall—

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

(B) as appropriate, revise such guidelines to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of an antibiotic drug under chapter
V of the Federal Food, Drug, and Cosmetic Act
(21 U.S.C. 351 et seq.).

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

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

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended
to be used to treat, detect, prevent, or identify a
qualifying pathogen may request that the Secretary
provide written recommendations for nonclinical and
clinical investigations which may be conducted with
the drug before it may be approved for such use
under section 505 of the Federal Food, Drug, and

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

(c) DEFINITIONS.—In this section:

(1) The term “drug” has the meaning given to
such term in section 201 of the Federal Food, Drug,

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

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