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111TH CONGRESS
2D SESSION

H. R. 6331

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 29, 2010

Mr. GINGREY of Georgia (for himself, Mr. GENE GREEN of Texas, Mr. WHITFIELD, Mr. ROGERS of Michigan, and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 2010''.

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.
Sec. 4. Priority review.

Sec. 5. Fast track product.
Sec. 6. Clinical trials.

SEC. 3. EXTENSION OF EXCLUSIVITY PERIOD.

(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 or licensure of a drug or biological product pursuant to an application that is submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act, the Secretary determines that the drug or biological product is a qualified infectious disease product, then the exclusivity period for such qualified infectious disease product is deemed to be extended by 5 years.

"(b) LIMITED TO FIRST LICENSURE.—Subsection (a) does not apply to the approval or licensure of—

"(1) a supplement for the qualified infectious disease product; or

"(2) a subsequent application filed by the same sponsor or manufacturer of the qualified infectious disease product (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—

''(i) safety or effectiveness in the case of a drug; or

''(ii) safety, purity, or potency in the case of a biological product.

''(c) DETERMINATION.—At the request of any person submitting an application described in subsection (a), the Secretary shall, not later than 30 days after the submission of such request and prior to approval of the application, determine whether the drug or biological product is a qualified infectious disease product.

''(d) 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 such date of enactment.

''(e) DEFINITIONS.—In this section:

''(1) EXCLUSIVITY PERIOD.—The term 'exclusivity period' means, with respect to a qualified in-

fectious disease product approved or licensed under section 505 of this Act or section 351 of the Public Health Service Act, the period of time (as extended under section 505A or 527 of this Act or section 351(m) of the Public Health Service Act) during which such section 505 or 351 prohibit the Secretary from making effective the approval of another application under such section 505 or 351 for such product for a person who is not the holder of such approved application or of such approved license.

''(2) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means an antibiotic drug, or a diagnostic test including a point-of-care diagnostic test, for treating, detecting, preventing, or identifying a qualifying pathogen.

''(3) QUALIFYING PATHOGEN.—The term 'qualifying pathogen' means—

''(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Staphylococcus aureus (VRSA), and vancomycin-resistant 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, in concurrence with infectious disease clinicians and appropriate professional associations, as a significant threat to public health because of drug resistance or other factors (or likely to become such a threat).".

(b) APPLICATION.—Section 505E of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall apply with respect to any drug or biological product that is first approved or licensed under section 505 of such Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date of the enactment of this Act.

SEC. 4. 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 determines under section 505E that a drug is a qualified infectious disease product, the Secretary shall give priority review to the application for approval or licensure of such product submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act.

''(b) DEFINITION.—In this section, the term 'priority review', with respect to an application described in subsection (b), 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), shall apply with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) on or after the date of the enactment of this Act.

SEC. 5. 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. 6. 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.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

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

(3) REPORTS TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, and annually thereafter for the next 4 years, the Secretary shall submit a report to the Congress on the progress of the review under paragraph (1).

(4) 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—

(A) it may be approved for such use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(B) if the drug is a biological product, it may be licensed for such use under section 351 of the Public Health Service Act.

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for—

(A) 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); or

(B) licensing under section 351 of the Public Health Service Act (42 U.S.C. 262) of such drug for such use.

(c) 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 ''drug'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) The term ''qualifying pathogen'' has the meaning given such term in section 505E of the

Federal Food, Drug, and Cosmetic Act, as added by section 3.

(4) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

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