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(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To provide for approval of certain drugs and biological products indicated for use in a limited population of patients in order to address increases in bacterial and fungal resistance to drugs and biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GINGREY of Georgia (for himself and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on _____

A BILL

To provide for approval of certain drugs and biological products indicated for use in a limited population of patients in order to address increases in bacterial and fungal resistance to drugs and biological products, and for other purposes.

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 ''Antibiotic Development to Advance Patient Treatment Act of 2013''.

SEC. 2. APPROVAL OF CERTAIN DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.

(a) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(x) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.—

''(1) APPROVAL.—At the request of the sponsor of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening disease or condition, the Secretary—

''(A) may approve the drug under subsection (c) to treat a limited population of patients for which there is an unmet medical need;

''(B) in determining whether to grant such approval for a limited population of patients, may rely on traditional endpoints, alternative endpoints, or a combination of traditional and alternative endpoints; datasets of limited size; pharmacologic or pathophysiologic data; data from phase 2 clinical studies; and such other confirmatory evidence as the Secretary deems necessary; and

''(C) shall require the labeling of drugs approved pursuant to this subsection to prominently include in the prescribing information required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

''(2) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval under this subsection to the same extent and in the same manner as such provisions apply with respect to accelerated approval under section 506(c)(1).

''(3) WITHDRAWAL OF LIMITED POPULATION APPROVAL REQUIREMENTS.—If a drug is approved pursuant to this subsection to treat a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, respectively, without such a limitation, the Secretary may remove any labeling requirements or postmarketing conditions made applicable to the drug during the earlier approval process.

''(4) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit designation and expedited review of a drug as a breakthrough therapy under section 506(a), designation and treatment of a drug as a fast track product under section 506(b), or accelerated approval of the drug under section 506(c), in combination with approval of the drug for use in a limited population of patients under this subsection.

''(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d)). Subsections (c) and (d) and such standards of evidence apply to the review and approval of drugs under this subsection, including whether a drug is safe and effective. Nothing in this subsection shall be construed to limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this subsection.

''(6) EFFECTIVE IMMEDIATELY.—The Secretary shall have the authorities vested in the Secretary by this subsection beginning on the date of enactment of this subsection, irrespective of when

and whether the Secretary promulgates final regulations to carry out this subsection.''.

(b) LICENSURE OF CERTAIN BIOLOGICAL PRODUCTS.—Section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)) is amended—

(1) by striking ''(j)'' and inserting ''(j)(1)'';

(2) by inserting ''505(x),'' after ''505(p),''; and

(3) by adding at the end the following:

''(2) In applying section 505(x) of the Federal Food, Drug, and Cosmetic Act to the licensure of biological products under this section—

''(A) references to an antibacterial or antifungal drug that is intended to treat a serious or life-threatening disease or condition shall be construed to refer to biological products intended to treat a bacterial or fungal infection associated with a serious or life-threatening disease; and

''(B) references to approval of a drug under section 505(c) of such Act shall be construed to refer to licensure of a biological product under subsection (a) of this section.''.

(c) MONITORING.—Title III of the Public Health Service Act is amended by inserting after section 317T (42 U.S.C. 247b–22) the following:

"SEC. 317U. MONITORING ANTIBACTERIAL AND ANTIFUNGAL DRUG USE AND RESISTANCE.

''(a) MONITORING.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall use the National Healthcare Safety Network or another appropriate monitoring system to monitor—

''(1) the use of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(x) of the Federal Food, Drug, and Cosmetic Act; and

''(2) changes in bacterial and fungal resistance to drugs.

''(b) PUBLIC AVAILABILITY OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make the data derived from monitoring under this section publicly available for the purposes of—

''(1) improving the monitoring of important trends in antibacterial and antifungal resistance; and

''(2) ensuring appropriate stewardship of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(x) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 3. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROBIAL ORGANISMS.

(a) IN GENERAL.—Section 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to read as follows:

"SEC. 511. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROBIAL ORGANISMS.

''(a) IN GENERAL.—The Secretary shall identify upon approval and subsequently update susceptibility test interpretive criteria for antibacterial drugs (including biological products intended to treat a bacterial infection and other types of antimicrobial drugs, as deemed appropriate by the Secretary), including qualified infectious disease products, by relying upon, to the extent available—

''(1) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

''(2) Bayesian and pharmacometric statistical methodologies; and

''(3) such other confirmatory evidence as the Secretary deems necessary.

''(b) RESPONDING TO SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA IDENTIFIED OR UPDATED BY PRIVATE ENTITIES.—

''(1) IN GENERAL.—Each quarter of each fiscal year, the Secretary shall—

''(A) evaluate any appropriate new or updated susceptibility test interpretive criteria published by a nationally or internationally recognized standard development organization; and

''(B) publish on the public Website of the Food and Drug Administration a notice—

''(i) adopting the new or updated interpretive criteria;

''(ii) declining to adopt the new or updated interpretive criteria and explaining the reason for such decision; or

''(iii) adopting one or more parts of the new or updated interpretive criteria, declining to adopt the remainder of such criteria, and explaining the reason for so declining.

''(2) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(B) and publish such compilation in the Federal Register.

''(3) RELATION TO SECTION 514(C).—Any susceptibility test interpretive criterion for which an approval is in effect under paragraph (1) may be recognized as a standard by the Secretary under section 514(c)(1).

''(4) USE OF NON-ADOPTED CRITERIA.—Nothing in this section prohibits the sponsor of a drug or device from seeking approval or clearance of the drug or device, or changes to the drug, the device, or its labeling, on the basis of susceptibility test interpretive criteria which differ from those adopted pursuant to paragraph (1).

''(c) DEFINITIONS.—In this section:

''(1) The term 'qualified infectious disease product' means a qualified infectious disease product designated under 505E(d).

''(2) The term 'susceptibility test interpretive criteria' means one or more specific values which characterize the degree to which bacteria or other microbes are resistant to the drug (or drugs) tested, such as clinically susceptible, intermediate, or resistant.''.

(b) CONFORMING AMENDMENT.—Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d–5a; relating to identification of clinically susceptible concentrations of antimicrobials) is repealed.

(c) REPORT TO CONGRESS.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Rep-

resentatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the progress made in implementing section 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as amended by this section.

SEC. 4. NO EFFECT ON HEALTH CARE PRACTICE.

Nothing in the Antibiotic Development to Advance Patient Treatment Act of 2013 (including the amendments made thereby) shall be construed to restrict, in any manner, the prescribing of antibiotics or other products by health care professionals, or to limit the practice of health care.