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(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Ms. DELAURO 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 well-defined population of patients in order to address increases in bacterial 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 ''Helping Effective Antibiotics Last Act of 2015'' or the ''HEAL Act''.

SEC. 2. APPROVAL OF CERTAIN DRUGS FOR USE IN A WELL-DEFINED POPULATION OF PATIENTS.

(a) APPROVAL OF CERTAIN ANTIBACTERIAL.—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 DRUGS FOR USE IN A WELL-DEFINED POPULATION OF PATIENTS.—

''(1) UNMET MEDICAL NEED DEFINED.—In this subsection, the term 'unmet medical need' means that the antibacterial drug involved—

''(A) has improved efficacy, as demonstrated in adequate, well-controlled studies in humans, for specific diseases or conditions, where current therapies have been shown to be less effective;

''(B) has clinically meaningful decreased harms, demonstrated in adequate, well-controlled studies in humans, for diseases or conditions, where current therapies have unacceptable adverse effects; or

''(C) has improved convenience, as demonstrated in adequate, well-controlled studies in humans, where improved convenience results in improved effectiveness or decreased harms.

''(2) APPROVAL.—Upon receipt of an application under subsection (b) for an antibacterial drug that is intended to treat a serious or life-threatening disease or condition, irrespective of whether the drug is intended to address an unmet medical need, the Secretary—

''(A) may approve the drug under subsection (c) only for treating a well-defined population of patients, and based upon the results of clinical trials inclusive of human subjects representative of such well-defined population;

''(B) in determining whether to grant such approval, shall rely on superior outcomes over available therapies based on direct measures of patient benefits, as demonstrated in adequate, well-controlled studies in the well-defined patient population, such as—

''(i) decreased mortality;

''(ii) irreversible morbidity; or

''(iii) validated surrogate endpoints that reflect mortality or irreversible morbidity; and

''(C) shall require the labeling of drugs approved pursuant to this subsection to prominently include in the prescribing information re-

quired by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation)—

''(i) the population of patients with respect to which the added benefit over available therapies is expected as studied in adequate, well-controlled studies that form the basis for approval; and

''(ii) the method for identifying members of that population.

''(3) RISK EVALUATION AND MITIGATION STRATEGY.—The Secretary—

''(A) shall require a risk evaluation and mitigation strategy (REMS) under section 505–1 for each drug approved under this subsection; and

''(B) may include in any such strategy additional elements to assure the safe use of the drug under subsections (e) and (f) of section 505–1.

''(4) 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.

''(5) 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 drug with added benefits over available therapies for a well-defined population that is intended to treat a serious

or life-threatening disease or condition shall be construed to refer to biological products with added benefits over available therapies for a well-defined population intended to treat a bacterial infection associated with a serious or life-threatening disease; and

''(B) references to an application submitted under section 505(b) of such Act and to approval of a drug under section 505(c) of such Act shall be construed to refer to an application submitted under subsection (a) of this section and to licensure of a biological product under such subsection (a), respectively.''.

(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 OF ANTIBACTERIAL DRUG USE, PATIENT OUTCOMES, 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) changes in patient outcomes such as mortality and irreversible morbidity causally related to antibacterial resistance; and

''(2) changes in bacterial resistance to drugs in relation to patient outcomes.

''(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 patient outcomes in relation to antibacterial resistance; and

''(2) ensuring appropriate stewardship of antibacterial drugs, including those receiving approval or licensure for a well-defined 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—

''(1) identify upon approval or licensing of antibacterial drugs (including biological products in-

tended to treat a bacterial infection and other types of antimicrobial drugs, as deemed appropriate by the Secretary), including qualified infectious disease products, susceptibility test interpretive criteria for such drugs based upon patient outcomes of mortality and morbidity from adequate and well-controlled studies and such other confirmatory evidence as the Secretary deems necessary; and

''(2) update, consistent with subsection (b), such criteria as needed based upon scientific evidence of changes in patient outcomes.

''(b) RESPONDING TO CHANGES IN PATIENT OUTCOMES TO EVALUATE SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA.—

''(1) IN GENERAL.—As needed based on evidence related to changes in patient outcomes, the Secretary shall—

''(A) evaluate any new scientific studies on changes in patient outcomes in relation to susceptibility test interpretive criteria; and

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

''(i) presenting suggested new or updated interpretive criteria; and

''(ii) if needed, hold a public advisory committee to discuss scientific evidence related to changes in interpretative criteria.

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

''(c) DEFINITION.—In this section, the term 'susceptibility test interpretive criteria' means one or more specific values which characterize patient outcomes in relation to the degree to which bacteria or other microbes are more resistant to treatment as measured by patient outcomes.''.

(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 Representatives 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. REQUIRING DEMONSTRATION OF SUPERIOR OUTCOMES FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS TO RECEIVE AN EXTENDED EXCLUSIVITY PERIOD.

Section 505E(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f(g)) is amended by striking ''means an antibacterial or antifungal drug for human use intended to treat'' and inserting ''means an antibacterial or antifungal drug for human use that is demonstrated to produce superior outcomes over available therapies, based on direct measures of patient benefits in clinical trials, and that is intended to treat''.

SEC. 5. GUIDANCE ON TARGET PRODUCT PROFILES.

Not later than 18 months after the date of enactment of this Act, the Commissioner of Food and Drugs, in consultation with the Administrator of the Centers for Medicare & Medicaid Services, the Director of the Indian Health Service, the Secretary of Defense, and the Secretary of Veterans Affairs, shall issue guidance on the development of target product profiles for novel antibacterial drugs focused on public health priorities.