

114TH CONGRESS  
1ST SESSION

# H. R. 931

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.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2015

Ms. DELAURO (for herself, Ms. SLAUGHTER, and Ms. MENG) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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.

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 “Helping Effective Anti-  
5 biotics Last Act of 2015” or the “HEAL Act”.

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

3 (a) APPROVAL OF CERTAIN ANTIBACTERIAL.—Sec-  
4 tion 505 of the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 355) is amended by adding at the end the fol-  
6 lowing:

7 “(x) APPROVAL OF CERTAIN ANTIBACTERIAL DRUGS  
8 FOR USE IN A WELL-DEFINED POPULATION OF PA-  
9 TIENTS.—

10 “(1) UNMET MEDICAL NEED DEFINED.—In this  
11 subsection, the term ‘unmet medical need’ means  
12 that the antibacterial drug involved—

13 “(A) has improved efficacy, as dem-  
14 onstrated in adequate, well-controlled studies in  
15 humans, for specific diseases or conditions,  
16 where current therapies have been shown to be  
17 less effective;

18 “(B) has clinically meaningful decreased  
19 harms, demonstrated in adequate, well-con-  
20 trolled studies in humans, for diseases or condi-  
21 tions, where current therapies have unaccept-  
22 able adverse effects; or

23 “(C) has improved convenience, as dem-  
24 onstrated in adequate, well-controlled studies in  
25 humans, where improved convenience results in  
26 improved effectiveness or decreased harms.

1           “(2) APPROVAL.—Upon receipt of an applica-  
2           tion under subsection (b) for an antibacterial drug  
3           that is intended to treat a serious or life-threatening  
4           disease or condition, irrespective of whether the drug  
5           is intended to address an unmet medical need, the  
6           Secretary—

7                   “(A) may approve the drug under sub-  
8                   section (c) only for treating a well-defined popu-  
9                   lation of patients, and based upon the results of  
10                  clinical trials inclusive of human subjects rep-  
11                  resentative of such well-defined population;

12                  “(B) in determining whether to grant such  
13                  approval, shall rely on superior outcomes over  
14                  available therapies based on direct measures of  
15                  patient benefits, as demonstrated in adequate,  
16                  well-controlled studies in the well-defined pa-  
17                  tient population, such as—

18                           “(i) decreased mortality;

19                           “(ii) irreversible morbidity; or

20                           “(iii) validated surrogate endpoints  
21                           that reflect mortality or irreversible mor-  
22                           bidity; and

23                  “(C) shall require the labeling of drugs ap-  
24                  proved pursuant to this subsection to promi-  
25                  nently include in the prescribing information re-

1           required by section 201.57 of title 21, Code of  
2           Federal Regulations (or any successor regula-  
3           tion)—

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

9                   “(ii) the method for identifying mem-  
10                  bers of that population.

11               “(3) RISK EVALUATION AND MITIGATION  
12               STRATEGY.—The Secretary—

13                   “(A) shall require a risk evaluation and  
14                   mitigation strategy (REMS) under section 505–  
15                   1 for each drug approved under this subsection;  
16                   and

17                   “(B) may include in any such strategy ad-  
18                   ditional elements to assure the safe use of the  
19                   drug under subsections (e) and (f) of section  
20                   505–1.

21               “(4) RULE OF CONSTRUCTION.—Nothing in  
22               this subsection shall be construed to alter the stand-  
23               ards of evidence under subsection (e) or (d) (includ-  
24               ing the substantial evidence standard in subsection  
25               (d)). Subsections (c) and (d) and such standards of

1 evidence apply to the review and approval of drugs  
2 under this subsection, including whether a drug is  
3 safe and effective. Nothing in this subsection shall  
4 be construed to limit the authority of the Secretary  
5 to approve products pursuant to this Act and the  
6 Public Health Service Act as authorized prior to the  
7 date of enactment of this subsection.

8 “(5) EFFECTIVE IMMEDIATELY.—The Sec-  
9 retary shall have the authorities vested in the Sec-  
10 retary by this subsection beginning on the date of  
11 enactment of this subsection, irrespective of when  
12 and whether the Secretary promulgates final regula-  
13 tions to carry out this subsection.”.

14 (b) LICENSURE OF CERTAIN BIOLOGICAL PROD-  
15 UCTS.—Section 351(j) of the Public Health Service Act  
16 (42 U.S.C. 262(j)) is amended—

- 17 (1) by striking “(j)” and inserting “(j)(1)”;
- 18 (2) by inserting “505(x),” after “505(p),”; and
- 19 (3) by adding at the end the following:

20 “(2) In applying section 505(x) of the Federal Food,  
21 Drug, and Cosmetic Act to the licensure of biological prod-  
22 ucts under this section—

23 “(A) references to an antibacterial drug with  
24 added benefits over available therapies for a well-de-  
25 fined population that is intended to treat a serious

1 or life-threatening disease or condition shall be con-  
2 strued to refer to biological products with added  
3 benefits over available therapies for a well-defined  
4 population intended to treat a bacterial infection as-  
5 sociated with a serious or life-threatening disease;  
6 and

7 “(B) references to an application submitted  
8 under section 505(b) of such Act and to approval of  
9 a drug under section 505(c) of such Act shall be  
10 construed to refer to an application submitted under  
11 subsection (a) of this section and to licensure of a  
12 biological product under such subsection (a), respec-  
13 tively.”.

14 (c) MONITORING.—Title III of the Public Health  
15 Service Act is amended by inserting after section 317T  
16 (42 U.S.C. 247b–22) the following:

17 **“SEC. 317U. MONITORING OF ANTIBACTERIAL DRUG USE,**  
18 **PATIENT OUTCOMES, AND RESISTANCE.**

19 “(a) MONITORING.—The Secretary, acting through  
20 the Director of the Centers for Disease Control and Pre-  
21 vention, shall use the National Healthcare Safety Network  
22 or another appropriate monitoring system to monitor—

23 “(1) changes in patient outcomes such as mor-  
24 tality and irreversible morbidity causally related to  
25 antibacterial resistance; and

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

3           “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-  
4           retary, acting through the Director of the Centers for Dis-  
5           ease Control and Prevention, shall make the data derived  
6           from monitoring under this section publicly available for  
7           the purposes of—

8                   “(1) improving the monitoring of important  
9                   trends in patient outcomes in relation to anti-  
10                  bacterial resistance; and

11                   “(2) ensuring appropriate stewardship of anti-  
12                  bacterial drugs, including those receiving approval or  
13                  licensure for a well-defined population pursuant to  
14                  section 505(x) of the Federal Food, Drug, and Cos-  
15                  metic Act.”.

16 **SEC. 3. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
17 **FOR MICROBIAL ORGANISMS.**

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

21 **“SEC. 511. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
22 **FOR MICROBIAL ORGANISMS.**

23           “(a) IN GENERAL.—The Secretary shall—

24                   “(1) identify upon approval or licensing of anti-  
25                  bacterial drugs (including biological products in-

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

9 “(2) update, consistent with subsection (b),  
10 such criteria as needed based upon scientific evi-  
11 dence of changes in patient outcomes.

12 “(b) RESPONDING TO CHANGES IN PATIENT OUT-  
13 COMES TO EVALUATE SUSCEPTIBILITY TEST INTERPRE-  
14 TIVE CRITERIA.—

15 “(1) IN GENERAL.—As needed based on evi-  
16 dence related to changes in patient outcomes, the  
17 Secretary shall—

18 “(A) evaluate any new scientific studies on  
19 changes in patient outcomes in relation to sus-  
20 ceptibility test interpretive criteria; and

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

23 “(i) presenting suggested new or up-  
24 dated interpretive criteria; and



1                   “(ii) if needed, hold a public advisory  
2                   committee to discuss scientific evidence re-  
3                   lated to changes in interpretative criteria.

4                   “(2) ANNUAL COMPILATION OF NOTICES.—  
5                   Each year, the Secretary shall compile the notices  
6                   published under paragraph (1)(B) noting any  
7                   changes from prior notices and publish such com-  
8                   pilation in the Federal Register.

9                   “(c) DEFINITION.—In this section, the term ‘suscep-  
10                  tibility test interpretive criteria’ means one or more spe-  
11                  cific values which characterize patient outcomes in relation  
12                  to the degree to which bacteria or other microbes are more  
13                  resistant to treatment as measured by patient outcomes.”.

14                  (b) CONFORMING AMENDMENT.—Section 1111 of the  
15                  Food and Drug Administration Amendments Act of 2007  
16                  (42 U.S.C. 247d–5a; relating to identification of clinically  
17                  susceptible concentrations of antimicrobials) is repealed.

18                  (c) REPORT TO CONGRESS.—Not later than one year  
19                  after the date of enactment of this Act, the Secretary of  
20                  Health and Human Services shall submit to the Com-  
21                  mittee on Energy and Commerce of the House of Rep-  
22                  resentatives and the Committee on Health, Education,  
23                  Labor, and Pensions of the Senate a report on the  
24                  progress made in implementing section 511 of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as  
2 amended by this section.

3 **SEC. 4. REQUIRING DEMONSTRATION OF SUPERIOR OUT-**  
4 **COMES FOR QUALIFIED INFECTIOUS DISEASE**  
5 **PRODUCTS TO RECEIVE AN EXTENDED EX-**  
6 **CLUSIVITY PERIOD.**

7 Section 505E(g) of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 355f(g)) is amended by striking  
9 “means an antibacterial or antifungal drug for human use  
10 intended to treat” and inserting “means an antibacterial  
11 or antifungal drug for human use that is demonstrated  
12 to produce superior outcomes over available therapies,  
13 based on direct measures of patient benefits in clinical  
14 trials, and that is intended to treat”.

15 **SEC. 5. GUIDANCE ON TARGET PRODUCT PROFILES.**

16 Not later than 18 months after the date of enactment  
17 of this Act, the Commissioner of Food and Drugs, in con-  
18 sultation with the Administrator of the Centers for Medi-  
19 care & Medicaid Services, the Director of the Indian  
20 Health Service, the Secretary of Defense, and the Sec-  
21 retary of Veterans Affairs, shall issue guidance on the de-  
22 velopment of target product profiles for novel antibacterial  
23 drugs focused on public health priorities.

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