

113TH CONGRESS  
1ST SESSION

# H. R. 3742

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.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 12, 2013

Mr. GINGREY of Georgia (for himself, Mr. GENE GREEN of Texas, Mr. SHIMKUS, Ms. ESHOO, Mr. WHITFIELD, Ms. DEGETTE, Mrs. BLACKBURN, Mr. ENGEL, Mr. GRIFFITH of Virginia, and Mr. BUTTERFIELD) 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 limited population of patients in order to address increases in bacterial and fungal 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 “Antibiotic Development  
5 to Advance Patient Treatment Act of 2013”.

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

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

7 “(x) APPROVAL OF CERTAIN ANTIBACTERIAL AND  
8 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-  
9 LATION OF PATIENTS.—

10 “(1) APPROVAL.—At the request of the sponsor  
11 of an antibacterial or antifungal drug that is in-  
12 tended to treat a serious or life-threatening disease  
13 or condition, the Secretary—

14 “(A) may approve the drug under sub-  
15 section (c) to treat a limited population of pa-  
16 tients for which there is an unmet medical  
17 need;

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

1           “(C) shall require the labeling of drugs ap-  
2           proved pursuant to this subsection to promi-  
3           nently include in the prescribing information re-  
4           quired by section 201.57 of title 21, Code of  
5           Federal Regulations (or any successor regula-  
6           tion) the following statement: ‘This drug is in-  
7           dicated for use in a limited and specific popu-  
8           lation of patients.’.

9           “(2) PROMOTIONAL MATERIALS.—The provi-  
10          sions of section 506(c)(2)(B) shall apply with re-  
11          spect to approval under this subsection to the same  
12          extent and in the same manner as such provisions  
13          apply with respect to accelerated approval under sec-  
14          tion 506(c)(1).

15          “(3) WITHDRAWAL OF LIMITED POPULATION  
16          APPROVAL REQUIREMENTS.—If a drug is approved  
17          pursuant to this subsection to treat a limited popu-  
18          lation of patients and is subsequently approved or li-  
19          censed under this section or section 351 of the Pub-  
20          lic Health Service Act, respectively, without such a  
21          limitation, the Secretary may remove any labeling  
22          requirements or postmarketing conditions made ap-  
23          plicable to the drug during the earlier approval proc-  
24          ess.

1           “(4) RELATION TO OTHER PROVISIONS.—Noth-  
2           ing in this subsection shall be construed to prohibit  
3           designation and expedited review of a drug as a  
4           breakthrough therapy under section 506(a), designa-  
5           tion and treatment of a drug as a fast track product  
6           under section 506(b), or accelerated approval of the  
7           drug under section 506(c), in combination with ap-  
8           proval of the drug for use in a limited population of  
9           patients under this subsection.

10           “(5) RULE OF CONSTRUCTION.—Nothing in  
11           this subsection shall be construed to alter the stand-  
12           ards of evidence under subsection (c) or (d) (includ-  
13           ing the substantial evidence standard in subsection  
14           (d)). Subsections (c) and (d) and such standards of  
15           evidence apply to the review and approval of drugs  
16           under this subsection, including whether a drug is  
17           safe and effective. Nothing in this subsection shall  
18           be construed to limit the authority of the Secretary  
19           to approve products pursuant to this Act and the  
20           Public Health Service Act as authorized prior to the  
21           date of enactment of this subsection.

22           “(6) EFFECTIVE IMMEDIATELY.—The Sec-  
23           retary shall have the authorities vested in the Sec-  
24           retary by this subsection beginning on the date of  
25           enactment of this subsection, irrespective of when

1 and whether the Secretary promulgates final regula-  
2 tions to carry out this subsection.”.

3 (b) LICENSURE OF CERTAIN BIOLOGICAL PROD-  
4 UCTS.—Section 351(j) of the Public Health Service Act  
5 (42 U.S.C. 262(j)) is amended—

6 (1) by striking “(j)” and inserting “(j)(1)”;

7 (2) by inserting “505(x),” after “505(p),”; and

8 (3) by adding at the end the following:

9 “(2) In applying section 505(x) of the Federal  
10 Food, Drug, and Cosmetic Act to the licensure of bi-  
11 ological products under this section—

12 “(A) references to an antibacterial or  
13 antifungal drug that is intended to treat a seri-  
14 ous or life-threatening disease or condition shall  
15 be construed to refer to biological products in-  
16 tended to treat a bacterial or fungal infection  
17 associated with a serious or life-threatening dis-  
18 ease; and

19 “(B) references to approval of a drug  
20 under section 505(c) of such Act shall be con-  
21 strued to refer to licensure of a biological prod-  
22 uct under subsection (a) of this section.”.

23 (c) MONITORING.—Title III of the Public Health  
24 Service Act is amended by inserting after section 317T  
25 (42 U.S.C. 247b–22) the following:

1 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**  
2 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

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

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

11 “(2) changes in bacterial and fungal resistance  
12 to drugs.

13 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-  
14 retary, acting through the Director of the Centers for Dis-  
15 ease Control and Prevention, shall make the data derived  
16 from monitoring under this section publicly available for  
17 the purposes of—

18 “(1) improving the monitoring of important  
19 trends in antibacterial and antifungal resistance;  
20 and

21 “(2) ensuring appropriate stewardship of anti-  
22 bacterial and antifungal drugs, including those re-  
23 ceiving approval or licensure for a limited population  
24 pursuant to section 505(x) of the Federal Food,  
25 Drug, and Cosmetic Act.”.

1 **SEC. 3. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
2 **FOR MICROBIAL ORGANISMS.**

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

6 **“SEC. 511. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
7 **FOR MICROBIAL ORGANISMS.**

8 “(a) IN GENERAL.—The Secretary shall identify  
9 upon approval and subsequently update susceptibility test  
10 interpretive criteria for antibacterial drugs (including bio-  
11 logical products intended to treat a bacterial infection and  
12 other types of antimicrobial drugs, as deemed appropriate  
13 by the Secretary), including qualified infectious disease  
14 products, by relying upon, to the extent available—

15 “(1) preclinical and clinical data, including  
16 pharmacokinetic, pharmacodynamic, and epidemio-  
17 logical data;

18 “(2) Bayesian and pharmacometric statistical  
19 methodologies; and

20 “(3) such other confirmatory evidence as the  
21 Secretary deems necessary.

22 “(b) RESPONDING TO SUSCEPTIBILITY TEST INTER-  
23 PRETIVE CRITERIA IDENTIFIED OR UPDATED BY PRI-  
24 VATE ENTITIES.—

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

1           “(A) evaluate any appropriate new or up-  
2           dated susceptibility test interpretive criteria  
3           published by a nationally or internationally rec-  
4           ognized standard development organization; and

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

7                   “(i) adopting the new or updated in-  
8                   terpretive criteria;

9                   “(ii) declining to adopt the new or up-  
10                  dated interpretive criteria and explaining  
11                  the reason for such decision; or

12                  “(iii) adopting one or more parts of  
13                  the new or updated interpretive criteria,  
14                  declining to adopt the remainder of such  
15                  criteria, and explaining the reason for so  
16                  declining.

17           “(2) ANNUAL COMPILATION OF NOTICES.—

18           Each year, the Secretary shall compile the notices  
19           published under paragraph (1)(B) and publish such  
20           compilation in the Federal Register.

21           “(3) RELATION TO SECTION 514(c).—Any sus-  
22           ceptibility test interpretive criterion for which an ap-  
23           proval is in effect under paragraph (1) may be rec-  
24           ognized as a standard by the Secretary under sec-  
25           tion 514(c)(1).



1           “(4) USE OF NON-ADOPTED CRITERIA.—Noth-  
2           ing in this section prohibits the sponsor of a drug  
3           or device from seeking approval or clearance of the  
4           drug or device, or changes to the drug, the device,  
5           or its labeling, on the basis of susceptibility test in-  
6           terpretive criteria which differ from those adopted  
7           pursuant to paragraph (1).

8           “(c) DEFINITIONS.—In this section:

9           “(1) The term ‘qualified infectious disease  
10           product’ means a qualified infectious disease product  
11           designated under 505E(d).

12           “(2) The term ‘susceptibility test interpretive  
13           criteria’ means one or more specific values which  
14           characterize the degree to which bacteria or other  
15           microbes are resistant to the drug (or drugs) tested,  
16           such as clinically susceptible, intermediate, or resist-  
17           ant.”.

18           (b) CONFORMING AMENDMENT.—Section 1111 of the  
19           Food and Drug Administration Amendments Act of 2007  
20           (42 U.S.C. 247d–5a; relating to identification of clinically  
21           susceptible concentrations of antimicrobials) is repealed.

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

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

6 **SEC. 4. NO EFFECT ON HEALTH CARE PRACTICE.**

7       Nothing in the Antibiotic Development to Advance  
8 Patient Treatment Act of 2013 (including the amend-  
9 ments made thereby) shall be construed to restrict, in any  
10 manner, the prescribing of antibiotics or other products  
11 by health care professionals, or to limit the practice of  
12 health care.

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