

114TH CONGRESS
1ST SESSION

H. R. 2629

To amend the Federal Food, Drug, and Cosmetic Act with respect to the approval of certain antibacterial and antifungal drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 3, 2015

Mr. SHIMKUS (for himself and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the approval of certain antibacterial and antifungal drugs, 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”.

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

8 (a) PURPOSE.—The purpose of this section is to help
9 expedite the development and availability of treatments for
10 serious or life-threatening bacterial or fungal infections in

1 patients with unmet needs, while maintaining safety and
2 effectiveness standards for such treatments, taking into
3 account the severity of the infection and the availability
4 or lack of alternative treatments.

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

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

12 “(1) PROCESS.—At the request of the sponsor
13 of an antibacterial or antifungal drug that is in-
14 tended to treat a serious or life-threatening infec-
15 tion, the Secretary—

16 “(A) may execute a written agreement
17 with the sponsor on the process for developing
18 data to support an application for approval of
19 such drug, for use in a limited population of pa-
20 tients in accordance with this subsection;

21 “(B) shall proceed in accordance with this
22 subsection only if a written agreement is
23 reached under subparagraph (A);

1 “(C) shall provide the sponsor with an op-
2 portunity to request meetings under paragraph
3 (2);

4 “(D) if a written agreement is reached
5 under subparagraph (A), may approve the drug
6 under this subsection for such use—

7 “(i) in a limited population of patients
8 for which there is an unmet medical need;

9 “(ii) based on a streamlined develop-
10 ment program; and

11 “(iii) only if the standards for ap-
12 proval under subsections (c) and (d) of this
13 section or licensure under section 351 of
14 the Public Health Service Act, as applica-
15 ble, are met; and

16 “(E) in approving a drug in accordance
17 with this subsection, subject to subparagraph
18 (D)(iii), may rely upon—

19 “(i) traditional endpoints, alternate
20 endpoints, or a combination of traditional
21 and alternate endpoints, and, as appro-
22 priate, data sets of a limited size; and

23 “(ii)(I) additional data, including pre-
24 clinical, pharmacologic, or pathophysiologic
25 evidence;

1 “(II) nonclinical susceptibility and
2 pharmacokinetic data;

3 “(III) data from phase 2 clinical
4 trials; and

5 “(IV) such other confirmatory evi-
6 dence as the Secretary determines appro-
7 priate to approve the drug.

8 “(2) FORMAL MEETINGS.—

9 “(A) IN GENERAL.—To help expedite and
10 facilitate the development and review of a drug
11 for which a sponsor intends to request approval
12 in accordance with this subsection, the Sec-
13 retary may, at the request of the sponsor, con-
14 duct meetings that provide early consultation,
15 timely advice, and sufficient opportunities to
16 develop an agreement described in paragraph
17 (1)(A) and help the sponsor design and conduct
18 a drug development program as efficiently as
19 possible, including the following types of meet-
20 ings:

21 “(i) An early consultation meeting.

22 “(ii) An assessment meeting.

23 “(iii) A postapproval meeting.

24 “(B) NO ALTERING OF GOALS.—Nothing
25 in this paragraph shall be construed to alter

1 agreed upon goals and procedures identified in
2 the letters described in section 101(b) of the
3 Prescription Drug User Fee Amendments of
4 2012.

5 “(C) BREAKTHROUGH THERAPIES.—In the
6 case of a drug designated as a breakthrough
7 therapy under section 506(a), the sponsor of
8 such drug may elect to utilize meetings pro-
9 vided under such section with respect to such
10 drug in lieu of meetings described in subpara-
11 graph (A).

12 “(3) LABELING REQUIREMENT.—The labeling
13 of an antibacterial or antifungal drug approved in
14 accordance with this subsection shall contain the
15 statement ‘Limited Population’ in a prominent man-
16 ner and adjacent to, and not more prominent than,
17 the brand name of the product. The prescribing in-
18 formation for such antibacterial or antifungal drug
19 required by section 201.57 of title 21, Code of Fed-
20 eral Regulations (or any successor regulation) shall
21 also include the following statement: ‘This drug is
22 indicated for use in a limited and specific population
23 of patients.’.

24 “(4) PROMOTIONAL MATERIALS.—The provi-
25 sions of section 506(e)(2)(B) shall apply with re-

1 spect to approval in accordance with this subsection
2 to the same extent and in the same manner as such
3 provisions apply with respect to accelerated approval
4 in accordance with section 506(c)(1).

5 “(5) TERMINATION OF REQUIREMENTS OR CON-
6 DITIONS.—If a drug is approved in accordance with
7 this subsection for an indication in a limited popu-
8 lation of patients and is subsequently approved or li-
9 censed under this section or section 351 of the Pub-
10 lic Health Service Act, other than in accordance with
11 this subsection, for—

12 “(A) the same indication and the same
13 conditions of use, the Secretary shall remove
14 any labeling requirements or postmarketing
15 conditions that were made applicable to the
16 drug under this subsection; or

17 “(B) a different indication or condition of
18 use, the Secretary shall not apply the labeling
19 requirements and postmarketing conditions that
20 were made applicable to the drug under this
21 subsection to the subsequent approval of the
22 drug for such different indication or condition
23 of use.

24 “(6) RELATION TO OTHER PROVISIONS.—Noth-
25 ing in this subsection shall be construed to prohibit

1 the approval of a drug for use in a limited popu-
2 lation of patients in accordance with this subsection,
3 in combination with—

4 “(A) an agreement on the design and size
5 of a clinical trial pursuant to subparagraphs
6 (B) and (C) of subsection (b)(5);

7 “(B) designation and treatment of the
8 drug as a breakthrough therapy under section
9 506(a);

10 “(C) designation and treatment of the
11 drug as a fast track product under section
12 506(b); or

13 “(D) accelerated approval of the drug in
14 accordance with section 506(e).

15 “(7) RULE OF CONSTRUCTION.—Nothing in
16 this subsection shall be construed—

17 “(A) to alter the standards of evidence
18 under subsection (e) or (d) (including the sub-
19 stantial evidence standard in subsection (d));

20 “(B) to waive or otherwise preclude the ap-
21 plication of requirements under subsection (o);

22 “(C) to otherwise, in any way, limit the au-
23 thority of the Secretary to approve products
24 pursuant to this Act and the Public Health

1 Service Act as authorized prior to the date of
2 enactment of this subsection; or

3 “(D) to restrict in any manner, the pre-
4 scribing of antibiotics or other products by
5 health care providers, or to otherwise limit or
6 restrict the practice of health care.

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

13 “(9) DEFINITIONS.—In this subsection:

14 “(A) EARLY CONSULTATION MEETING.—
15 The term ‘early consultation meeting’ means a
16 pre-investigational new drug meeting or an end-
17 of-phase 1 meeting that—

18 “(i) is conducted to review and reach
19 a written agreement—

20 “(I) on the scope of the stream-
21 lined development plan for a drug for
22 which a sponsor intends to request ap-
23 proval in accordance with this sub-
24 section; and

1 “(II) which, as appropriate, may
2 include agreement on the design and
3 size of necessary preclinical and clin-
4 ical studies early in the development
5 process, including clinical trials whose
6 data are intended to form the primary
7 basis for an effectiveness claim; and

8 “(ii) provides an opportunity to dis-
9 cuss expectations of the Secretary regard-
10 ing studies or other information that the
11 Secretary deems appropriate for purposes
12 of applying paragraph (5), relating to the
13 termination of labeling requirements or
14 postmarketing conditions.

15 “(B) ASSESSMENT MEETING.—The term
16 ‘assessment meeting’ means an end-of-phase 2
17 meeting, pre-new drug application meeting, or
18 pre-biologics license application meeting con-
19 ducted to resolve questions and issues raised
20 during the course of clinical investigations, and
21 details addressed in the written agreement re-
22 garding postapproval commitments or expan-
23 sion of approved uses.

24 “(C) POSTAPPROVAL MEETING.—The term
25 ‘postapproval meeting’ means a meeting fol-

1 lowing initial approval or licensure of the drug
2 for use in a limited population, to discuss any
3 issues identified by the Secretary or the sponsor
4 regarding postapproval commitments or expansion
5 of approved uses.”.

6 (c) GUIDANCE.—Not later than 18 months after the
7 date of enactment of this Act, the Secretary of Health and
8 Human Services, acting through the Commissioner of
9 Food and Drugs, shall issue draft guidance describing cri-
10 teria, process, and other general considerations for dem-
11 onstrating the safety and effectiveness of antibacterial and
12 antifungal drugs to be approved for use in a limited popu-
13 lation in accordance with section 505(x) of the Federal
14 Food, Drug, and Cosmetic Act, as added by subsection
15 (b).

16 (d) CONFORMING AMENDMENTS.—

17 (1) LICENSURE OF CERTAIN BIOLOGICAL PROD-
18 UCTS.—Section 351(j) of the Public Health Service
19 Act (42 U.S.C. 262(j)) is amended—

20 (A) by striking “(j)” and inserting
21 “(j)(1)”;

22 (B) by inserting “505(x),” after “505(p),”;
23 and

24 (C) by adding at the end the following new
25 paragraph:

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

4 “(A) references to an antibacterial or antifungal
5 drug that is intended to treat a serious or life-
6 threatening infection shall be construed to refer to
7 a biological product intended to treat a serious or
8 life-threatening bacterial or fungal infection; and

9 “(B) references to approval of a drug under
10 section 505(c) of such Act shall be construed to
11 refer to a licensure of a biological product under
12 subsection (a) of this section.”.

13 (2) MISBRANDING.—Section 502 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is
15 amended by adding at the end the following new
16 subsection:

17 “(dd) If it is a drug approved in accordance with sec-
18 tion 505(x) and its labeling does not meet the require-
19 ments under paragraph (3) of such subsection, subject to
20 paragraph (5) of such subsection.”.

21 (e) EVALUATION.—

22 (1) ASSESSMENT.—Not later than 48 months
23 after the date of enactment of this Act, the Sec-
24 retary of Health and Human Services shall publish
25 for public comment an assessment of the program

1 established under section 505(x) of the Federal
2 Food, Drug, and Cosmetic Act, as added by sub-
3 section (b). Such assessment shall determine if the
4 limited-use pathway established under such section
5 505(x) has improved or is likely to improve patient
6 access to novel antibacterial or antifungal treat-
7 ments and assess how the pathway could be ex-
8 panded to cover products for serious or life-threat-
9 ening diseases or conditions beyond bacterial and
10 fungal infections.

11 (2) MEETING.—Not later than 90 days after
12 the date of the publication of such assessment, the
13 Secretary, acting through the Commissioner of Food
14 and Drugs shall hold a public meeting to discuss the
15 findings of the assessment, during which public
16 stakeholders may present their views on the success
17 of the program established under section 505(x) of
18 the Federal Food, Drug, and Cosmetic Act, as
19 added by subsection (b), and the appropriateness of
20 expanding such program.

21 (f) EXPANSION OF PROGRAM.—If the Secretary of
22 Health and Human Services determines, based on the as-
23 sessment under subsection (e)(1), evaluation of the assess-
24 ment, and any other relevant information, that the public
25 health would benefit from expansion of the limited-use

1 pathway established under section 505(x) of the Federal
2 Food, Drug, and Cosmetic Act (as added by subsection
3 (b)) beyond the drugs approved in accordance with such
4 section, the Secretary may expand such limited-use path-
5 way in accordance with such a determination. The ap-
6 proval of any drugs under any such expansion shall be
7 subject to the considerations and requirements described
8 in such section 505(x) for purposes of expansion to other
9 serious or life-threatening diseases or conditions.

10 (g) MONITORING.—The Public Health Service Act is
11 amended by inserting after section 317T (42 U.S.C.
12 247b–22) the following:

13 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**
14 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

15 “(a) MONITORING.—The Secretary shall use an ap-
16 propriate monitoring system to monitor—

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

21 “(2) changes in bacterial and fungal resistance
22 to drugs.

23 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-
24 retary shall make summaries of the data derived from

1 monitoring under this section publicly available for the
2 purposes of—

3 “(1) improving the monitoring of important
4 trends in antibacterial and antifungal resistance;
5 and

6 “(2) ensuring appropriate stewardship of anti-
7 bacterial and antifungal drugs, including those re-
8 ceiving approval or licensure for a limited population
9 pursuant to section 505(x) of the Federal Food,
10 Drug, and Cosmetic Act.”.

11 **SEC. 3. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**
12 **FOR MICROORGANISMS.**

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

16 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**
17 **TEST INTERPRETIVE CRITERIA FOR MICRO-**
18 **ORGANISMS.**

19 “(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

20 “(1) PURPOSE.—The purpose of this section is
21 to provide the Secretary with an expedited, flexible
22 method for—

23 “(A) clearance or premarket approval of
24 antimicrobial susceptibility testing devices uti-
25 lizing updated, recognized susceptibility test in-

1 terpretive criteria to characterize the in vitro
2 susceptibility of particular bacteria, fungi, or
3 other microorganisms to antimicrobial drugs;
4 and

5 “(B) providing public notice of the avail-
6 ability of recognized interpretive criteria to
7 meet premarket submission requirements or
8 other requirements under this Act for anti-
9 microbial susceptibility testing devices.

10 “(2) IN GENERAL.—The Secretary shall iden-
11 tify appropriate susceptibility test interpretive cri-
12 teria with respect to antimicrobial drugs—

13 “(A) if such criteria are available on the
14 date of approval of the drug under section 505
15 of this Act or licensure of the drug under sec-
16 tion 351 of the Public Health Service Act (as
17 applicable), upon such approval or licensure; or

18 “(B) if such criteria are unavailable on
19 such date, on the date on which such criteria
20 are available for such drug.

21 “(3) BASES FOR INITIAL IDENTIFICATION.—
22 The Secretary shall identify appropriate suscepti-
23 bility test interpretive criteria under paragraph (2),
24 based on the Secretary’s review of, to the extent
25 available and relevant—

1 “(A) preclinical and clinical data, including
2 pharmacokinetic, pharmacodynamic, and epide-
3 miological data;

4 “(B) Bayesian and pharmacometric statis-
5 tical methodologies; and

6 “(C) such other evidence and information
7 as the Secretary considers appropriate.

8 “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA
9 WEBSITE.—

10 “(1) IN GENERAL.—Not later than 1 year after
11 the date of the enactment of the Antibiotic Develop-
12 ment to Advance Patient Treatment Act, the Sec-
13 retary shall establish, and maintain thereafter, on
14 the website of the Food and Drug Administration, a
15 dedicated website that contains a list of any appro-
16 priate new or updated susceptibility test interpretive
17 criteria standards in accordance with paragraph (2)
18 (referred to in this section as the ‘Interpretive Cri-
19 teria Website’).

20 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-
21 PRETIVE CRITERIA STANDARDS.—

22 “(A) IN GENERAL.—The list described in
23 paragraph (1) shall consist of any new or up-
24 dated susceptibility test interpretive criteria
25 standards that are—

1 “(i) established by a nationally or
2 internationally recognized standard devel-
3 opment organization that—

4 “(I) establishes and maintains
5 procedures to address potential con-
6 flicts of interest and ensure trans-
7 parent decisionmaking;

8 “(II) holds open meetings to en-
9 sure that there is an opportunity for
10 public input by interested parties, and
11 establishes and maintains processes to
12 ensure that such input is considered
13 in decisionmaking; and

14 “(III) permits its standards to be
15 made publicly available, through the
16 National Library of Medicine or an-
17 other similar source acceptable to the
18 Secretary; and

19 “(ii) recognized in whole, or in part,
20 by the Secretary under subsection (e).

21 “(B) OTHER LIST.—The Interpretive Cri-
22 teria Website shall, in addition to the list de-
23 scribed in subparagraph (A), include a list of
24 interpretive criteria, if any, that the Secretary
25 has determined to be appropriate with respect

1 to legally marketed antimicrobial drugs,
2 where—

3 “(i) the Secretary does not recognize,
4 in whole or in part, an interpretive criteria
5 standard described under subparagraph
6 (A) otherwise applicable to such a drug;

7 “(ii) the Secretary withdraws under
8 subsection (c)(1)(B) recognition of a
9 standard, in whole or in part, otherwise
10 applicable to such a drug;

11 “(iii) the Secretary approves an appli-
12 cation under section 505 of this Act or sec-
13 tion 351 of the Public Health Service Act,
14 as applicable, with respect to marketing of
15 such a drug for which there are no rel-
16 evant interpretive criteria included in a
17 standard recognized by the Secretary
18 under subsection (c); or

19 “(iv) because the characteristics of
20 such a drug differ from other drugs with
21 the same active ingredient, the interpretive
22 criteria with respect to such drug—

23 “(I) differ from otherwise appli-
24 cable interpretive criteria included in
25 a standard listed under subparagraph

1 (A) or interpretive criteria otherwise
2 listed under this subparagraph; and

3 “(II) are determined by the Sec-
4 retary to be appropriate for the drug.

5 “(C) REQUIRED STATEMENTS OF LIMITA-
6 TIONS OF INFORMATION.—The Interpretive Cri-
7 teria Website shall include the following:

8 “(i) A statement that—

9 “(I) the website provides infor-
10 mation about the susceptibility of bac-
11 teria, fungi, or other microorganisms
12 to a certain drug (or drugs); and

13 “(II) the safety and efficacy of
14 the drug in treating clinical infections
15 due to such bacteria, fungi, or other
16 microorganisms may not have been es-
17 tablished in adequate and well-con-
18 trolled clinical trials and the clinical
19 significance of such susceptibility in-
20 formation in such trials is unknown.

21 “(ii) A statement that directs health
22 care practitioners to consult the approved
23 product labeling for specific drugs to deter-
24 mine the uses for which the Food and

1 Drug Administration has approved the
2 product.

3 “(iii) Any other statement that the
4 Secretary determines appropriate to ade-
5 quately convey the limitations of the data
6 supporting susceptibility test interpretive
7 criteria standard listed on the website.

8 “(3) NOTICE.—Not later than the date on
9 which the Interpretive Criteria Website is estab-
10 lished, the Secretary shall publish a notice of that
11 establishment in the Federal Register.

12 “(4) INAPPLICABILITY OF MISBRANDING PROVI-
13 SION.—The inclusion in the approved labeling of an
14 antimicrobial drug of a reference or hyperlink to the
15 Interpretive Criteria Website, in and of itself, shall
16 not cause the drug to be misbranded in violation of
17 section 502, or the regulations promulgated there-
18 under.

19 “(5) TRADE SECRETS AND CONFIDENTIAL IN-
20 FORMATION.—Nothing in this section shall be con-
21 strued as authorizing the Secretary to disclose any
22 information that is a trade secret or confidential in-
23 formation subject to section 552(b)(4) of title 5,
24 United States Code.

1 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-
2 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-
3 GANIZATIONS.—

4 “(1) IN GENERAL.—Beginning on the date of
5 the establishment of the Interpretive Criteria
6 Website, and at least every 6 months thereafter, the
7 Secretary shall—

8 “(A) evaluate any appropriate new or up-
9 dated susceptibility test interpretive criteria
10 standards established by a nationally or inter-
11 nationally recognized standard development or-
12 ganization described in subsection (b)(2)(A)(i);
13 and

14 “(B) publish on the public website of the
15 Food and Drug Administration a notice—

16 “(i) withdrawing recognition of any
17 different susceptibility test interpretive cri-
18 teria standard, in whole or in part;

19 “(ii) recognizing the new or updated
20 standards;

21 “(iii) recognizing one or more parts of
22 the new or updated interpretive criteria
23 specified in such a standard and declining
24 to recognize the remainder of such stand-
25 ard; and

1 “(iv) making any necessary updates to
2 the lists under subsection (b)(2).

3 “(2) BASES FOR UPDATING INTERPRETIVE CRI-
4 TERIA STANDARDS.—In evaluating new or updated
5 susceptibility test interpretive criteria standards
6 under paragraph (1)(A), the Secretary may con-
7 sider—

8 “(A) the Secretary’s determination that
9 such a standard is not applicable to a particular
10 drug because the characteristics of the drug dif-
11 fer from other drugs with the same active in-
12 gredient;

13 “(B) information provided by interested
14 third parties, including public comment on the
15 annual compilation of notices published under
16 paragraph (3);

17 “(C) any bases used to identify suscepti-
18 bility test interpretive criteria under subsection
19 (a)(2); and

20 “(D) such other information or factors as
21 the Secretary determines appropriate.

22 “(3) ANNUAL COMPILATION OF NOTICES.—
23 Each year, the Secretary shall compile the notices
24 published under paragraph (1)(B) and publish such
25 compilation in the Federal Register and provide for

1 public comment. If the Secretary receives comments,
2 the Secretary will review such comments and, if the
3 Secretary determines appropriate, update pursuant
4 to this subsection susceptibility test interpretive cri-
5 teria standards—

6 “(A) recognized by the Secretary under
7 this subsection; or

8 “(B) otherwise listed on the Interpretive
9 Criteria Website under subsection (b)(2).

10 “(4) RELATION TO SECTION 514(c).—Any sus-
11 ceptibility test interpretive standard recognized
12 under this subsection or any criteria otherwise listed
13 under subsection (b)(2)(B) shall be deemed to be
14 recognized as a standard by the Secretary under sec-
15 tion 514(c)(1).

16 “(5) VOLUNTARY USE OF INTERPRETIVE CRI-
17 TERIA.—Nothing in this section prohibits a person
18 from seeking approval or clearance of a drug or de-
19 vice, or changes to the drug or the device, on the
20 basis of susceptibility test interpretive criteria stand-
21 ards which differ from those recognized pursuant to
22 paragraph (1).

23 “(d) ANTIMICROBIAL DRUG LABELING.—

24 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-
25 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With

1 respect to an antimicrobial drug lawfully introduced
2 or delivered for introduction into interstate com-
3 merce for commercial distribution before the estab-
4 lishment of the Interpretive Criteria Website, a hold-
5 er of an approved application under section 505 or
6 section 351 of the Public Health Service Act, as ap-
7 plicable, for each such drug—

8 “(A) not later than 1 year after establish-
9 ment of the Interpretive Criteria Website, shall
10 submit to the Secretary a supplemental applica-
11 tion for purposes of changing the drug’s label-
12 ing to substitute a reference or hyperlink to
13 such Website for any susceptibility test inter-
14 pretive criteria and related information; and

15 “(B) may begin distribution of the drug in-
16 volved upon receipt by the Secretary of the sup-
17 plemental application for such change.

18 “(2) DRUGS MARKETED SUBSEQUENT TO ES-
19 TABLISHMENT OF INTERPRETIVE CRITERIA
20 WEBSITE.—With respect to antimicrobial drugs law-
21 fully introduced or delivered for introduction into
22 interstate commerce for commercial distribution on
23 or after the date of the establishment of the Inter-
24 pretive Criteria Website, the labeling for such a drug
25 shall include, in lieu of susceptibility test interpretive

1 criteria and related information, a reference to such
2 Website.

3 “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-
4 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

5 “(1) IN GENERAL.—Notwithstanding sections
6 501, 502, 510, 513, and 515, if the conditions speci-
7 fied in paragraph (2) are met (in addition to other
8 applicable provisions under this chapter) with re-
9 spect to an antimicrobial susceptibility testing device
10 described in subsection (f)(1), the Secretary may au-
11 thorize the marketing of such device for a use de-
12 scribed in such subsection.

13 “(2) CONDITIONS APPLICABLE TO ANTI-
14 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

15 The conditions specified in this paragraph are the
16 following:

17 “(A) The device is used to make a deter-
18 mination of susceptibility using susceptibility
19 test interpretive criteria that are—

20 “(i) included in a standard recognized
21 by the Secretary under subsection (c); or

22 “(ii) otherwise listed on the Interpre-
23 tive Criteria Website under subsection
24 (b)(2).

1 “(B) The labeling of such device promi-
2 nently and conspicuously—

3 “(i) includes a statement that—

4 “(I) the device provides informa-
5 tion about the susceptibility of bac-
6 teria and fungi to certain drugs; and

7 “(II) the safety and efficacy of
8 such drugs in treating clinical infec-
9 tions due to such bacteria or fungi
10 may not have been established in ade-
11 quate and well-controlled clinical trials
12 and the clinical significance of such
13 susceptibility information in those in-
14 stances is unknown;

15 “(ii) includes a statement directing
16 health care practitioners to consult the ap-
17 proved labeling for drugs tested using such
18 a device, to determine the uses for which
19 the Food and Drug Administration has ap-
20 proved such drugs; and

21 “(iii) includes any other statement the
22 Secretary determines appropriate to ade-
23 quately convey the limitations of the data
24 supporting the interpretive criteria de-
25 scribed in subparagraph (A).

1 “(f) DEFINITIONS.—In this section:

2 “(1) The term ‘antimicrobial susceptibility test-
3 ing device’ means a device that utilizes susceptibility
4 test interpretive criteria to determine and report the
5 in vitro susceptibility of certain microorganisms to a
6 drug (or drugs).

7 “(2) The term ‘qualified infectious disease
8 product’ means a qualified infectious disease product
9 designated under section 505E(d).

10 “(3) The term ‘susceptibility test interpretive
11 criteria’ means—

12 “(A) one or more specific numerical values
13 which characterize the susceptibility of bacteria
14 or other microorganisms to the drug tested; and

15 “(B) related categorizations of such sus-
16 ceptibility, including categorization of the drug
17 as susceptible, intermediate, resistant, or such
18 other term as the Secretary determines appro-
19 priate.

20 “(4)(A) The term ‘antimicrobial drug’ means,
21 subject to subparagraph (B), a systemic anti-
22 bacterial or antifungal drug that—

23 “(i) is intended for human use in the treat-
24 ment of a disease or condition caused by a bac-
25 terium or fungus;

1 “(ii) may include a qualified infectious dis-
2 ease product designated under section 505E(d);
3 and

4 “(iii) is subject to section 503(b)(1).

5 “(B) If provided by the Secretary through regu-
6 lations, such term may include—

7 “(i) drugs other than systemic anti-
8 bacterial and antifungal drugs; and

9 “(ii) biological products (as such term is
10 defined in section 351 of the Public Health
11 Service Act) to the extent such products exhibit
12 antimicrobial activity.

13 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
14 tion shall be construed—

15 “(1) to alter the standards of evidence—

16 “(A) under subsection (c) or (d) of section
17 505, including the substantial evidence stand-
18 ard in section 505(d), or under section 351 of
19 the Public Health Service Act (as applicable);
20 or

21 “(B) with respect to marketing authoriza-
22 tion for devices, under section 510, 513, or 515;

23 “(2) to apply with respect to any drug, device,
24 or biological product, in any context other than—

25 “(A) an antimicrobial drug; or

1 “(B) an antimicrobial susceptibility testing
2 device that uses susceptibility test interpretive
3 criteria to characterize and report the in vitro
4 susceptibility of certain bacteria, fungi, or other
5 microorganisms to antimicrobial drugs in ac-
6 cordance with this section; or

7 “(3) unless specifically stated, to have any ef-
8 fect on authorities provided under other sections of
9 this Act, including any regulations issued under such
10 sections.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) REPEAL OF RELATED AUTHORITY.—Section
13 1111 of the Food and Drug Administration Amend-
14 ments Act of 2007 (42 U.S.C. 247d–5a; relating to
15 identification of clinically susceptible concentrations
16 of antimicrobials) is repealed.

17 (2) MISBRANDING.—Section 502 of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 352), as
19 amended by section 1, is further amended by adding
20 at the end the following:

21 “(ee) If it is an antimicrobial drug and its labeling
22 fails to conform with the requirements under section
23 511(d).”.

24 (3) RECOGNITION OF INTERPRETIVE CRITERIA
25 AS DEVICE STANDARD.—Section 514(c)(1)(A) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 360d(e)(1)(A)) is amended by inserting after “the
3 Secretary shall, by publication in the Federal Reg-
4 ister” the following: “(or, with respect to suscepti-
5 bility test interpretive criteria or standards recog-
6 nized or otherwise listed under section 511, by post-
7 ing on the Interpretive Criteria Website in accord-
8 ance with such section)”.

9 (c) REPORT TO CONGRESS.—Not later than two
10 years after the date of enactment of this Act, the Sec-
11 retary of Health and Human Services shall submit to the
12 Committee on Energy and Commerce of the House of
13 Representatives and the Committee on Health, Education,
14 Labor, and Pensions of the Senate a report on the
15 progress made in implementing section 511 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as
17 amended by this section.

18 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-
19 TERIA WEBSITE.—Chapter 35 of title 44, United States
20 Code, shall not apply to the collection of information from
21 interested parties regarding the updating of lists under
22 paragraph (2) of subsection (b) of section 511 of the Fed-
23 eral Food, Drug, and Cosmetic Act (as amended by sub-
24 section (a)) and posted on the Interpretive Criteria

1 Website established under paragraph (1) of such sub-
2 section (b).

3 (e) NO EFFECT ON HEALTH CARE PRACTICE.—

4 Nothing in this Act (including the amendments made by
5 this Act) shall be construed to restrict, in any manner,
6 the prescribing or administering of antibiotics or other
7 products by health care practitioners, or to limit the prac-
8 tice of health care.

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