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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

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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.

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''.

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

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

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

(b) 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 new subsection:

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

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

''(A) may execute a written agreement with the sponsor on the process for developing data to support an application for approval of such drug, for use in a limited population of patients in accordance with this subsection;

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

"(C) shall provide the sponsor with an opportunity to request meetings under paragraph (2);

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

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

"(ii) based on a streamlined development program; and

"(iii) only if the standards for approval under subsections (c) and (d) of this section or licensure under section 351 of the Public Health Service Act, as applicable, are met; and

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

"(i) traditional endpoints, alternate endpoints, or a combination of traditional and alternate endpoints, and, as appropriate, data sets of a limited size; and

"(ii)(I) additional data, including preclinical, pharmacologic, or pathophysiologic evidence;

"(II) nonclinical susceptibility and pharmacokinetic data;

"(III) data from phase 2 clinical trials; and

"(IV) such other confirmatory evidence as the Secretary determines appropriate to approve the drug.

"(2) FORMAL MEETINGS.—

"(A) IN GENERAL.—To help expedite and facilitate the development and review of a drug for which a sponsor intends to request approval in accordance with this subsection, the Secretary may, at the request of the sponsor, conduct meetings that provide early consultation, timely advice, and sufficient opportunities to develop an agreement described in paragraph (1)(A) and help the sponsor design and conduct a drug development program as efficiently as possible, including the following types of meetings:

"(i) An early consultation meeting.

"(ii) An assessment meeting.

"(iii) A postapproval meeting.

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

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

''(C) BREAKTHROUGH THERAPIES.—In the case of a drug designated as a breakthrough therapy under section 506(a), the sponsor of such drug may elect to utilize meetings provided under such section with respect to such drug in lieu of meetings described in subparagraph (A).

''(3) LABELING REQUIREMENT.—The labeling of an antibacterial or antifungal drug approved in accordance with this subsection shall contain the statement 'Limited Population' in a prominent manner and adjacent to, and not more prominent than, the brand name of the product. The prescribing information for such antibacterial or antifungal drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

''(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with re-

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

''(5) TERMINATION OF REQUIREMENTS OR CONDITIONS.—If a drug is approved in accordance with this subsection for an indication in a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, other than in accordance with this subsection, for—

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

''(B) a different indication or condition of use, the Secretary shall not apply the labeling requirements and postmarketing conditions that were made applicable to the drug under this subsection to the subsequent approval of the drug for such different indication or condition of use.

''(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit

the approval of a drug for use in a limited population of patients in accordance with this subsection, in combination with—

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

"(B) designation and treatment of the drug as a breakthrough therapy under section 506(a);

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

"(D) accelerated approval of the drug in accordance with section 506(c).

"(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

"(A) to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d));

"(B) to waive or otherwise preclude the application of requirements under subsection (o);

"(C) to otherwise, in any way, 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; or

"(D) to restrict in any manner, the prescribing of antibiotics or other products by health care providers, or to otherwise limit or restrict the practice of health care.

"(8) 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 or guidance.

"(9) DEFINITIONS.—In this subsection:

"(A) EARLY CONSULTATION MEETING.—The term 'early consultation meeting' means a pre-investigational new drug meeting or an end-of-phase 1 meeting that—

"(i) is conducted to review and reach a written agreement—

"(I) on the scope of the streamlined development plan for a drug for which a sponsor intends to request approval in accordance with this subsection; and

''(II) which, as appropriate, may include agreement on the design and size of necessary preclinical and clinical studies early in the development process, including clinical trials whose data are intended to form the primary basis for an effectiveness claim; and

''(ii) provides an opportunity to discuss expectations of the Secretary regarding studies or other information that the Secretary deems appropriate for purposes of applying paragraph (5), relating to the termination of labeling requirements or postmarketing conditions.

''(B) ASSESSMENT MEETING.—The term 'assessment meeting' means an end-of-phase 2 meeting, pre-new drug application meeting, or pre-biologics license application meeting conducted to resolve questions and issues raised during the course of clinical investigations, and details addressed in the written agreement regarding postapproval commitments or expansion of approved uses.

''(C) POSTAPPROVAL MEETING.—The term 'postapproval meeting' means a meeting fol-

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

(c) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance describing criteria, process, and other general considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs to be approved for use in a limited population in accordance with section 505(x) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(d) CONFORMING AMENDMENTS.—

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

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

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

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

''(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 infection shall be construed to refer to a biological product intended to treat a serious or life-threatening bacterial or fungal infection; and

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

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

''(dd) If it is a drug approved in accordance with section 505(x) and its labeling does not meet the requirements under paragraph (3) of such subsection, subject to paragraph (5) of such subsection.''.

(e) EVALUATION.—

(1) ASSESSMENT.—Not later than 48 months after the date of enactment of this Act, the Secretary of Health and Human Services shall publish for public comment an assessment of the program

established under section 505(x) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b). Such assessment shall determine if the limited-use pathway established under such section 505(x) has improved or is likely to improve patient access to novel antibacterial or antifungal treatments and assess how the pathway could be expanded to cover products for serious or life-threatening diseases or conditions beyond bacterial and fungal infections.

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

(f) EXPANSION OF PROGRAM.—If the Secretary of Health and Human Services determines, based on the assessment under subsection (e)(1), evaluation of the assessment, and any other relevant information, that the public health would benefit from expansion of the limited-use

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

(g) MONITORING.—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 shall use an 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 shall make summaries of 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 MICROORGANISMS.

(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. IDENTIFYING AND UPDATING SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

''(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

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

''(A) clearance or premarket approval of antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test in-

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

"(B) providing public notice of the availability of recognized interpretive criteria to meet premarket submission requirements or other requirements under this Act for antimicrobial susceptibility testing devices.

"(2) IN GENERAL.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

"(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

"(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

"(3) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

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

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

''(C) such other evidence and information as the Secretary considers appropriate.

''(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Antibiotic Development to Advance Patient Treatment Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

''(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS.—

''(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

"(i) established by a nationally or internationally recognized standard development organization that—

"(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

"(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decisionmaking; and

"(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

"(ii) recognized in whole, or in part, by the Secretary under subsection (c).

"(B) OTHER LIST.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect

to legally marketed antimicrobial drugs, where—

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

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

"(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

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

"(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph

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

"(II) are determined by the Secretary to be appropriate for the drug.

"(C) REQUIRED STATEMENTS OF LIMITATIONS OF INFORMATION.—The Interpretive Criteria Website shall include the following:

"(i) A statement that—

"(I) the website provides information about the susceptibility of bacteria, fungi, or other microorganisms to a certain drug (or drugs); and

"(II) the safety and efficacy of the drug in treating clinical infections due to such bacteria, fungi, or other microorganisms may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in such trials is unknown.

"(ii) A statement that directs health care practitioners to consult the approved product labeling for specific drugs to determine the uses for which the Food and

Drug Administration has approved the product.

''(iii) Any other statement that the Secretary determines appropriate to adequately convey the limitations of the data supporting susceptibility test interpretive criteria standard listed on the website.

''(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

''(4) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502, or the regulations promulgated thereunder.

''(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

''(c) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FROM STANDARD DEVELOPMENT ORGANIZATIONS.—

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

''(A) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

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

''(i) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

''(ii) recognizing the new or updated standards;

''(iii) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

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

''(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

''(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

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

''(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

''(D) such other information or factors as the Secretary determines appropriate.

''(3) 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 and provide for

public comment. If the Secretary receives comments, the Secretary will review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards—

"(A) recognized by the Secretary under this subsection; or

"(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(4) RELATION TO SECTION 514(c).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 514(c)(1).

"(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria standards which differ from those recognized pursuant to paragraph (1).

"(d) ANTIMICROBIAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With

respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 or section 351 of the Public Health Service Act, as applicable, for each such drug—

"(A) not later than 1 year after establishment of the Interpretive Criteria Website, shall submit to the Secretary a supplemental application for purposes of changing the drug's labeling to substitute a reference or hyperlink to such Website for any susceptibility test interpretive criteria and related information; and

"(B) may begin distribution of the drug involved upon receipt by the Secretary of the supplemental application for such change.

"(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs lawfully introduced or delivered for introduction into interstate commerce for commercial distribution on or after the date of the establishment of the Interpretive Criteria Website, the labeling for such a drug shall include, in lieu of susceptibility test interpretive

criteria and related information, a reference to such Website.

''(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

''(1) IN GENERAL.—Notwithstanding sections 501, 502, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

''(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

''(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

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

''(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(B) The labeling of such device prominently and conspicuously—

"(i) includes a statement that—

"(I) the device provides information about the susceptibility of bacteria and fungi to certain drugs; and

"(II) the safety and efficacy of such drugs in treating clinical infections due to such bacteria or fungi may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in those instances is unknown;

"(ii) includes a statement directing health care practitioners to consult the approved labeling for drugs tested using such a device, to determine the uses for which the Food and Drug Administration has approved such drugs; and

"(iii) includes any other statement the Secretary determines appropriate to adequately convey the limitations of the data supporting the interpretive criteria described in subparagraph (A).

''(f) DEFINITIONS.—In this section:

''(1) The term 'antimicrobial susceptibility testing device' means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

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

''(3) The term 'susceptibility test interpretive criteria' means—

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

''(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

''(4)(A) The term 'antimicrobial drug' means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

''(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

''(ii) may include a qualified infectious disease product designated under section 505E(d); and

''(iii) is subject to section 503(b)(1).

''(B) If provided by the Secretary through regulations, such term may include—

''(i) drugs other than systemic antibacterial and antifungal drugs; and

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

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

''(1) to alter the standards of evidence—

''(A) under subsection (c) or (d) of section 505, including the substantial evidence standard in section 505(d), or under section 351 of the Public Health Service Act (as applicable); or

''(B) with respect to marketing authorization for devices, under section 510, 513, or 515;

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

''(A) an antimicrobial drug; or

''(B) an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the in vitro susceptibility of certain bacteria, fungi, or other microorganisms to antimicrobial drugs in accordance with this section; or

''(3) unless specifically stated, to have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.''.

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF RELATED AUTHORITY.—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.

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

''(ee) If it is an antimicrobial drug and its labeling fails to conform with the requirements under section 511(d).''.

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

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after ''the Secretary shall, by publication in the Federal Register'' the following: ''(or, with respect to susceptibility test interpretive criteria or standards recognized or otherwise listed under section 511, by posting on the Interpretive Criteria Website in accordance with such section)''.

(c) REPORT TO CONGRESS.—Not later than two years 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.

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding the updating of lists under paragraph (2) of subsection (b) of section 511 of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) and posted on the Interpretive Criteria

Website established under paragraph (1) of such subsection (b).

(e) NO EFFECT ON HEALTH CARE PRACTICE.—Nothing in this Act (including the amendments made by this Act) shall be construed to restrict, in any manner, the prescribing or administering of antibiotics or other products by health care practitioners, or to limit the practice of health care.

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