.....

(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to encourage the development of priority antimicrobial products through the award of a transferable exclusivity extension period, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. SHIMKUS introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to encourage the development of priority antimicrobial products through the award of a transferable exclusivity extension period, 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 ''Re-Valuing Anti-Microbial Products Act of 2018'' or the ''REVAMP Act''.

SEC. 2. EXCLUSIVITY TO ENCOURAGE DEVELOPMENT OF NOVEL THERAPIES TARGETING SERIOUS MICROBIAL INFECTIONS.

Subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by inserting after section 529A the following:

"SEC. 530. EXCLUSIVITY TO ENCOURAGE DEVELOPMENT OF NOVEL THERAPIES TARGETING SERIOUS MICROBIAL INFECTIONS.

''(a) IN GENERAL.—If the Secretary approves an application pursuant to section 505(c) of this Act or section 351(a) of the Public Health Service Act for a drug that has been designated as a priority antimicrobial product under subsection (k), the Secretary shall award to the holder of the application a 12-month exclusivity extension period described in subsection (c) for the sole purpose of conveying such extension, in whole or in portions, to other sponsors or holders to be applied with respect to one or more other drugs—

''(1) for which an application is submitted under section 505(b)(1);

''(2) for which at approval, new chemical entity exclusivity is granted under subsection (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505; and

''(3) that is designated as a fast track product under section 506(b).

''(b) NOTICE TO SECRETARY.—Upon making a conveyance under subsection (a), the holder of the approved application for the priority antimicrobial product involved shall submit a notice to the Secretary including—

''(1) the name of the priority antimicrobial product;

''(2) the name of the recipient drug; and

''(3) the duration of the conveyed exclusivity extension period.

''(c) EFFECT OF CONVEYANCE.—

''(1) EXTENSION OF OTHER APPLICABLE EXCLUSIVITY PERIODS.—Immediately upon the Secretary's receipt of a notice under subsection (b), with respect to the recipient drug, the following exclusivity periods (as applicable) are each extended by the conveyed exclusivity extension period:

''(A) The 4-year, 5-year, 48-month, and 7 ½ year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505.

''(B) The 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505.

''(C) The 7-year period described in section 527.

''(2) DRUGS SUBJECT TO LISTED PATENTS.—Immediately upon the Secretary's receipt of a notice under subsection (b), the period during which an approval of an application may not be made effective by operation of subsection (c)(3) or (j)(5)(B) of section 505, as applicable, in the case of a recipient drug that is the subject of—

''(A) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505;

''(B) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505; or

''(C) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 if in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed,

shall be extended after the date the listed patent expires (including any patent extensions) for a period equal to the conveyed exclusivity extension period.

''(d) TIMING OF CONVEYANCE AND NOTICE.—The conveyance of an exclusivity extension period pursuant to

subsection (a) and the provision of notice under subsection (b) shall be made no later than—

''(1) in the case of a priority antimicrobial product that is a drug, the last day of the ninth year of the 5-year period described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), as extended, as applicable, under section 505E; and

''(2) in the case of a priority antimicrobial product that is a biological product, the last day of the eleventh year of the exclusivity period described in section 351(k)(7)(A) of the Public Health Service Act applicable with respect to such product.

''(e) PERMITTED TRANSACTIONS.— Except as provided in this section, the holder of a conveyed exclusivity extension period may sell, exchange, convey, or hold for use, such period.

''(f) EXCEPTION.—A period referred to in paragraph (1) or (2) of subsection (c) shall not be extended under such subsection if the conveyance of an exclusivity extension period pursuant to subsection (a) or the provision of notice under subsection (b) is made later than 4 years prior to the expiration of such period.

''(g) LIMITATIONS.—

''(1) NUMBER OF AWARDS.—The Secretary may make not more than 10 awards under subsection (a).

''(2) AWARD FOR PRIOR APPROVED APPLICATION.—A drug is not eligible for designation under this section as a priority antimicrobial product if an application for approval or licensure of such drug was approved under section 505(b) or licensed under section 351(a) of the Public Health Service Act before January 1, 2018.

''(3) DRUGS INTENDED FOR COSMETIC PURPOSE.—A drug is not eligible for designation under this section as a priority antimicrobial product if the drug is intended to promote hair growth or for any other cosmetic purpose.

''(4) CONVEYANCE DATE.—The holder of an exclusivity extension period awarded under or conveyed pursuant to subsection (a) may not convey such period to be applied with respect to a drug unless such drug is or will be first approved under section 505(c) on or after January 1, 2023.

''(h) CONTRIBUTION UPON CONVEYANCE.—As a condition on the award of an exclusivity extension period to the holder of a drug pursuant to subsection (a), the Secretary shall require the holder, upon any conveyance of

the period pursuant to such subsection, in whole or in portions, to make a monetary contribution to the Foundation for the National Institutes of Health that—

''(1) is in an amount that is equal to 5 percent of the total value of the consideration received by the holder as a result of the conveyance; and

''(2) is designated to be used by the Foundation to conduct or support early-stage research on the development of products to treat or prevent a disease attributable to a multi-drug resistant bacterial or fungal pathogen.

''(i) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension of a period under subsection (c) shall be in addition to any extension of the period under section 505A of this Act, and any reference to a period in subsection (c) is deemed to be a reference to the period as extended under such section 505A, if applicable.

''(j) CRITICAL NEED ANTIMICROBIAL PRIORITIES.—

''(1) COMMITTEE ON DEVELOPING CRITICAL NEED ANTIMICROBIALS.—Not later than 60 days after the date of enactment of the Re-Valuing Anti-Microbial Products Act of 2018, the Secretary shall establish a Committee on Developing Critical Need Antimicrobials.

''(2) MEMBERSHIP.—The members of the Committee shall include—

''(A) one representative of the Food and Drug Administration;

''(B) one representative of the Centers for Disease Control and Prevention;

''(C) one representative of the Biomedical Advanced Research and Development Authority; and

''(D) five representatives of the community of other stakeholders with research, commercialization, clinical, public health, and economic expertise in the field of antimicrobial resistance, which representatives shall include at least one physician with experience treating infections caused by multidrug resistant organisms.

''(3) DUTIES.—The Committee shall—

''(A) not later than 60 days after all of the initial members of the Committee have been appointed, develop and publish on the website of the Office of the Assistant Secretary for Preparedness and Response a proposed list of critical need antimicrobial priorities consisting of specific multi-drug resistant bacterial or fungal

pathogens, which list shall be developed taking into consideration—

''(i) specific prevention or treatment of bacterial or fungal infections for which there is an unmet medical need; and

''(ii) susceptibility to specific microorganisms and treatment need for multidrug resistant pathogens;

''(B) perform other activities, as determined necessary by the Secretary, to support the designation of priority antimicrobial products under subsection (k) and the review and disposition of applications for priority antimicrobial products under subsection (a); and

''(C) develop recommendations to the Secretary and the Congress regarding other incentives needed to ensure a robust and renewable pipeline of antimicrobial drugs, with priority given to antimicrobial drugs that are first in class, possess a novel mechanism of action, or treat a vulnerable population such as children.

''(4) FINALIZATION AND UPDATING OF LIST OF CRITICAL NEED ANTIMICROBIALS PRIORITIES.—Upon receipt from the Committee of the initial pro-

posed list of critical need antimicrobial priorities or proposed updates to such list, the Secretary shall—

"(A) provide a period of public notice and comment on the proposal, including by publishing the proposed list on the Internet;

"(B) hold public meetings to elicit input from stakeholders on the proposal; and

"(C) not later than 180 days after the Secretary's receipt of the proposal, publish a final version of the list.

"(5) SUBSEQUENT UPDATES.—The Secretary, in coordination with the Committee, shall revise, and publish in accordance with paragraph (4), the list of critical need antimicrobial priorities within 30 days of approval of a product designated under subsection (k) or if the Secretary determines it is necessary, but in any case no later than every 2 years.

"(6) RESTRICTION ON REMOVAL FROM LIST.—No critical need antimicrobial priority may be removed from the list of critical need antimicrobial priorities until after submission of the report required by subsection (n)(1).

"(k) DESIGNATION OF PRIORITY ANTIMICROBIAL PRODUCTS.—

''(1) REQUEST.—The manufacturer or sponsor of a drug may request that the Secretary designate a drug as a priority antimicrobial product at any time before or after submission of an application for approval or licensure of such drug under section 505(b) of this Act or section 351(a) of the Public Health Service Act, as applicable.

''(2) DESIGNATION.—Not later than 60 days after the submission of a request under paragraph (1), the Secretary, in coordination with the Committee, shall—

''(A)(i) approve the request if the drug subject to the request is intended to treat or prevent a disease attributable to a multi-drug resistant bacterial or fungal pathogen that is listed as a critical need antimicrobial priority pursuant to subsection (j); or

''(ii) disapprove the request if the drug subject to the request is not intended to treat or prevent such a disease; and

''(B) notify the requestor of such action and, for any disapproval, include in such notification an explanation of the reason for the disapproval.

''(3) LIMITATION.—A designation under paragraph (2) shall not be withdrawn for any reason, including modifications to the list of critical need antimicrobial priorities, unless the Secretary finds that the request for such designation contained an untrue statement of material fact.

''(l) ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—As a condition on designation of a priority antimicrobial product pursuant to subsection (k), the sponsor of such product shall—

''(1) make such product available to antimicrobial susceptibility test device manufacturers as early in the development process as possible; and

''(2) submit a plan for such availability to the Secretary.

''(m) APPROPRIATE USE.—As a condition on designation of a priority antimicrobial product pursuant to subsection (k), the sponsor of such product shall agree to—

''(1) identify, track, and make publicly available antimicrobial resistance occurrence data and trends for such product;

''(2) develop, through the sponsor's chief compliance officer, the sponsor's chief medical officer, or another appropriate designee, written guidelines and

procedures to ensure appropriate use of such product, including appropriate—

''(A) promotional practices;

''(B) education to encourage appropriate use;

''(C) surveillance and monitoring; and

''(D) stewardship;

''(3) develop education and communications strategies for educating health care professionals about such product and its appropriate use; and

''(4) submit to the Food and Drug Administration, beginning at 24 months after the date of approval pursuant to section 505(c) of this Act or section 351(a) of the Public Health Service Act of an application for such product, and every two years thereafter so long as such product is marketed in the United States, an assessment of the sponsor's stewardship activities relating to such product.

''(n) STUDIES.—

''(1) JOINT STUDY BY HHS AND GAO.—

''(A) IN GENERAL.—Beginning 5 years after the date of enactment of the Re-Valuing Anti-Microbial Products Act of 2018 or on the date that the Secretary awards the fifth exclusivity extension period under this section,

whichever is earlier, the Director of the Centers for Disease Control and Prevention and Comptroller General of the United States shall conduct a study of the effectiveness of the program under this section for the development of priority antimicrobial products.

''(B) CONTENTS OF THE STUDY.—In conducting the study under subparagraph (A), the Director of the Centers for Disease Control and Prevention and Comptroller General shall examine—

''(i) the indications and usage for each drug for which an exclusivity extension period was awarded under subsection (a);

''(ii) the development of resistance to each drug for which an exclusivity extension period was awarded under subsection (a);

''(iii) the private and societal value of each drug for which an exclusivity extension period was awarded under subsection (a); and

''(iv) the impact on patients and public and private markets of the recipient

drug with respect to which a conveyed exclusivity extension period was used.

''(C) REPORT.—Not later than 1 year after the date by which the study under subparagraph (A) is required to begin under subparagraph (A), the Director of the Centers for Disease Control and Prevention and Comptroller General shall submit to the Congress a report containing the results of the study.

''(2) STUDY BY GAO.—Not later than the date that is 5 years after the date of the first award under subsection (a), the Comptroller General of the United States shall—

''(A) complete a study on the actual and projected impacts of the program under this section on Federal expenditures; and

''(B) submit a report on the results of such study to the Congress.

''(o) REPORT ON REAUTHORIZATION.—Not later than 180 days after the Secretary awards the ninth exclusivity extension period under this section, the Committee shall submit a report to the Secretary and the Congress containing recommendations on the reauthorization of this section, including recommendations on increasing the number of awards allowed by subsection (g)(1).

''(p) DEFINITIONS.—In this section:

''(1) The term 'biological product' has the meaning given to such term in section 351(i) of the Public Health Service Act.

''(2) The term 'Committee' means the Committee on Developing Critical Need Antimicrobials established under subsection (j).

''(3) The term 'conveyed exclusivity extension period' means an exclusivity extension period conveyed pursuant to subsection (a).

''(4) The term 'priority antimicrobial product' means a product that is designated under subsection (k).

''(5) The term 'recipient drug' means a drug approved under section 505 receiving a conveyed exclusivity extension period.''.