

115TH CONGRESS
2D SESSION

H. R. 6294

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

JUNE 28, 2018

Mr. SHIMKUS (for himself and Mr. CÁRDENAS) 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 to encourage the development of priority antimicrobial products through the award of a transferable exclusivity extension period, 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 “Re-Valuing Anti-Mi-
5 crobial Products Act of 2018” or the “REVAMP Act”.

1 **SEC. 2. EXCLUSIVITY TO ENCOURAGE DEVELOPMENT OF**
2 **NOVEL THERAPIES TARGETING SERIOUS MI-**
3 **CROBIAL INFECTIONS.**

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

7 **“SEC. 530. EXCLUSIVITY TO ENCOURAGE DEVELOPMENT OF**
8 **NOVEL THERAPIES TARGETING SERIOUS MI-**
9 **CROBIAL INFECTIONS.**

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

20 “(1) for which an application is submitted
21 under section 505(b)(1);

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

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

1 “(b) NOTICE TO SECRETARY.—Upon making a con-
2 veyance under subsection (a), the holder of the approved
3 application for the priority antimicrobial product involved
4 shall submit a notice to the Secretary including—

5 “(1) the name of the priority antimicrobial
6 product;

7 “(2) the name of the recipient drug; and

8 “(3) the duration of the conveyed exclusivity ex-
9 tension period.

10 “(c) EFFECT OF CONVEYANCE.—

11 “(1) EXTENSION OF OTHER APPLICABLE EX-
12 CLUSIVITY PERIODS.—Immediately upon the Sec-
13 retary’s receipt of a notice under subsection (b),
14 with respect to the recipient drug, the following ex-
15 clusivity periods (as applicable) are each extended by
16 the conveyed exclusivity extension period:

17 “(A) The 4-year, 5-year, 48-month, and
18 7½-year periods described in subsections
19 (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505.

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

24 “(C) The 7-year period described in section
25 527.

1 “(2) DRUGS SUBJECT TO LISTED PATENTS.—

2 Immediately upon the Secretary’s receipt of a notice
3 under subsection (b), the period during which an ap-
4 proval of an application may not be made effective
5 by operation of subsection (c)(3) or (j)(5)(B) of sec-
6 tion 505, as applicable, in the case of a recipient
7 drug that is the subject of—

8 “(A) a listed patent for which a certifi-
9 cation has been submitted under subsection
10 (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505;

11 “(B) a listed patent for which a certifi-
12 cation has been submitted under subsection
13 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section
14 505; or

15 “(C) a listed patent for which a certifi-
16 cation has been submitted under subsection
17 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505
18 if in the patent infringement litigation resulting
19 from the certification the court determines that
20 the patent is valid and would be infringed,
21 shall be extended after the date the listed patent ex-
22 pires (including any patent extensions) for a period
23 equal to the conveyed exclusivity extension period.

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

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

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

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

13 “(e) PERMITTED TRANSACTIONS.—Except as pro-
14 vided in this section, the holder of a conveyed exclusivity
15 extension period may sell, exchange, convey, or hold for
16 use, such period.

17 “(f) EXCEPTION.—A period referred to in paragraph
18 (1) or (2) of subsection (c) shall not be extended under
19 such subsection if the conveyance of an exclusivity exten-
20 sion period pursuant to subsection (a) or the provision of
21 notice under subsection (b) is made later than 4 years
22 prior to the expiration of such period.

23 “(g) LIMITATIONS.—

1 “(1) NUMBER OF AWARDS.—The Secretary
2 may make not more than 10 awards under sub-
3 section (a).

4 “(2) AWARD FOR PRIOR APPROVED APPLICA-
5 TION.—A drug is not eligible for designation under
6 this section as a priority antimicrobial product if an
7 application for approval or licensure of such drug
8 was approved under section 505(b) or licensed under
9 section 351(a) of the Public Health Service Act be-
10 fore January 1, 2018.

11 “(3) DRUGS INTENDED FOR COSMETIC PUR-
12 POSE.—A drug is not eligible for designation under
13 this section as a priority antimicrobial product if the
14 drug is intended to promote hair growth or for any
15 other cosmetic purpose.

16 “(4) CONVEYANCE DATE.—The holder of an ex-
17 clusivity extension period awarded under or conveyed
18 pursuant to subsection (a) may not convey such pe-
19 riod to be applied with respect to a drug unless such
20 drug is or will be first approved under section 505(c)
21 on or after January 1, 2023.

22 “(h) CONTRIBUTION UPON CONVEYANCE.—As a con-
23 dition on the award of an exclusivity extension period to
24 the holder of a drug pursuant to subsection (a), the Sec-
25 retary shall require the holder, upon any conveyance of

1 the period pursuant to such subsection, in whole or in por-
2 tions, to make a monetary contribution to the Foundation
3 for the National Institutes of Health that—

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

7 “(2) is designated to be used by the Foundation
8 to conduct or support early-stage research on the de-
9 velopment of products to treat or prevent a disease
10 attributable to a multi-drug resistant bacterial or
11 fungal pathogen.

12 “(i) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
13 extension of a period under subsection (c) shall be in addi-
14 tion to any extension of the period under section 505A
15 of this Act, and any reference to a period in subsection
16 (c) is deemed to be a reference to the period as extended
17 under such section 505A, if applicable.

18 “(j) CRITICAL NEED ANTIMICROBIAL PRIORITIES.—

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

1 “(2) MEMBERSHIP.—The members of the Com-
2 mittee shall include—

3 “(A) one representative of the Food and
4 Drug Administration;

5 “(B) one representative of the Centers for
6 Disease Control and Prevention;

7 “(C) one representative of the Biomedical
8 Advanced Research and Development Authority;
9 and

10 “(D) five representatives of the community
11 of other stakeholders with research, commer-
12 cialization, clinical, public health, and economic
13 expertise in the field of antimicrobial resistance,
14 which representatives shall include at least one
15 physician with experience treating infections
16 caused by multidrug resistant organisms.

17 “(3) DUTIES.—The Committee shall—

18 “(A) not later than 60 days after all of the
19 initial members of the Committee have been ap-
20 pointed, develop and publish on the website of
21 the Office of the Assistant Secretary for Pre-
22 paredness and Response a proposed list of crit-
23 ical need antimicrobial priorities consisting of
24 specific multi-drug resistant bacterial or fungal

1 pathogens, which list shall be developed taking
2 into consideration—

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

6 “(ii) susceptibility to specific micro-
7 organisms and treatment need for multi-
8 drug resistant pathogens;

9 “(B) perform other activities, as deter-
10 mined necessary by the Secretary, to support
11 the designation of priority antimicrobial prod-
12 ucts under subsection (k) and the review and
13 disposition of applications for priority anti-
14 microbial products under subsection (a); and

15 “(C) develop recommendations to the Sec-
16 retary and the Congress regarding other incen-
17 tives needed to ensure a robust and renewable
18 pipeline of antimicrobial drugs, with priority
19 given to antimicrobial drugs that are first in
20 class, possess a novel mechanism of action, or
21 treat a vulnerable population such as children.

22 “(4) FINALIZATION AND UPDATING OF LIST OF
23 CRITICAL NEED ANTIMICROBIALS PRIORITIES.—

24 Upon receipt from the Committee of the initial pro-

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

3 “(A) provide a period of public notice and
4 comment on the proposal, including by pub-
5 lishing the proposed list on the Internet;

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

8 “(C) not later than 180 days after the Sec-
9 retary’s receipt of the proposal, publish a final
10 version of the list.

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

18 “(6) RESTRICTION ON REMOVAL FROM LIST.—
19 No critical need antimicrobial priority may be re-
20 moved from the list of critical need antimicrobial
21 priorities until after submission of the report re-
22 quired by subsection (n)(1).

23 “(k) DESIGNATION OF PRIORITY ANTIMICROBIAL
24 PRODUCTS.—

1 “(1) REQUEST.—The manufacturer or sponsor
2 of a drug may request that the Secretary designate
3 a drug as a priority antimicrobial product at any
4 time before or after submission of an application for
5 approval or licensure of such drug under section
6 505(b) of this Act or section 351(a) of the Public
7 Health Service Act, as applicable.

8 “(2) DESIGNATION.—Not later than 60 days
9 after the submission of a request under paragraph
10 (1), the Secretary, in coordination with the Com-
11 mittee, shall—

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

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

21 “(B) notify the requestor of such action
22 and, for any disapproval, include in such notifi-
23 cation an explanation of the reason for the dis-
24 approval.

1 “(3) LIMITATION.—A designation under para-
2 graph (2) shall not be withdrawn for any reason, in-
3 cluding modifications to the list of critical need anti-
4 microbial priorities, unless the Secretary finds that
5 the request for such designation contained an untrue
6 statement of material fact.

7 “(1) ANTIMICROBIAL SUSCEPTIBILITY TESTING DE-
8 VICES.—As a condition on designation of a priority anti-
9 microbial product pursuant to subsection (k), the sponsor
10 of such product shall—

11 “(1) make such product available to anti-
12 microbial susceptibility test device manufacturers as
13 early in the development process as possible; and

14 “(2) submit a plan for such availability to the
15 Secretary.

16 “(m) APPROPRIATE USE.—As a condition on des-
17 ignation of a priority antimicrobial product pursuant to
18 subsection (k), the sponsor of such product shall agree
19 to—

20 “(1) identify, track, and make publicly available
21 antimicrobial resistance occurrence data and trends
22 for such product;

23 “(2) develop, through the sponsor’s chief com-
24 pliance officer, the sponsor’s chief medical officer, or
25 another appropriate designee, written guidelines and

1 procedures to ensure appropriate use of such prod-
2 uct, including appropriate—

3 “(A) promotional practices;

4 “(B) education to encourage appropriate
5 use;

6 “(C) surveillance and monitoring; and

7 “(D) stewardship;

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

11 “(4) submit to the Food and Drug Administra-
12 tion, beginning at 24 months after the date of ap-
13 proval pursuant to section 505(c) of this Act or sec-
14 tion 351(a) of the Public Health Service Act of an
15 application for such product, and every two years
16 thereafter so long as such product is marketed in
17 the United States, an assessment of the sponsor’s
18 stewardship activities relating to such product.

19 “(n) STUDIES.—

20 “(1) JOINT STUDY BY HHS AND GAO.—

21 “(A) IN GENERAL.—Beginning 5 years
22 after the date of enactment of the Re-Valuing
23 Anti-Microbial Products Act of 2018 or on the
24 date that the Secretary awards the fifth exclu-
25 sivity extension period under this section,

1 whichever is earlier, the Director of the Centers
2 for Disease Control and Prevention and Comp-
3 troller General of the United States shall con-
4 duct a study of the effectiveness of the program
5 under this section for the development of pri-
6 ority antimicrobial products.

7 “(B) CONTENTS OF THE STUDY.—In con-
8 ducting the study under subparagraph (A), the
9 Director of the Centers for Disease Control and
10 Prevention and Comptroller General shall exam-
11 ine—

12 “(i) the indications and usage for
13 each drug for which an exclusivity exten-
14 sion period was awarded under subsection
15 (a);

16 “(ii) the development of resistance to
17 each drug for which an exclusivity exten-
18 sion period was awarded under subsection
19 (a);

20 “(iii) the private and societal value of
21 each drug for which an exclusivity exten-
22 sion period was awarded under subsection
23 (a); and

24 “(iv) the impact on patients and pub-
25 lic and private markets of the recipient

1 drug with respect to which a conveyed ex-
2 clusivity extension period was used.

3 “(C) REPORT.—Not later than 1 year
4 after the date by which the study under sub-
5 paragraph (A) is required to begin under sub-
6 paragraph (A), the Director of the Centers for
7 Disease Control and Prevention and Comp-
8 troller General shall submit to the Congress a
9 report containing the results of the study.

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

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

17 “(B) submit a report on the results of such
18 study to the Congress.

19 “(o) REPORT ON REAUTHORIZATION.—Not later
20 than 180 days after the Secretary awards the ninth exclu-
21 sivity extension period under this section, the Committee
22 shall submit a report to the Secretary and the Congress
23 containing recommendations on the reauthorization of this
24 section, including recommendations on increasing the
25 number of awards allowed by subsection (g)(1).

1 “(p) DEFINITIONS.—In this section:

2 “(1) The term ‘biological product’ has the
3 meaning given to such term in section 351(i) of the
4 Public Health Service Act.

5 “(2) The term ‘Committee’ means the Com-
6 mittee on Developing Critical Need Antimicrobials
7 established under subsection (j).

8 “(3) The term ‘conveyed exclusivity extension
9 period’ means an exclusivity extension period con-
10 veyed pursuant to subsection (a).

11 “(4) The term ‘priority antimicrobial product’
12 means a product that is designated under subsection
13 (k).

14 “(5) The term ‘recipient drug’ means a drug
15 approved under section 505 receiving a conveyed ex-
16 clusivity extension period.”.

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