

118TH CONGRESS
1ST SESSION

S. 1355

To establish a program to develop antimicrobial innovations targeting the most challenging pathogens and most threatening infections, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 27, 2023

Mr. BENNET (for himself and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish a program to develop antimicrobial innovations targeting the most challenging pathogens and most threatening infections, 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 “Pioneering Anti-
5 microbial Subscriptions To End Upsurging Resistance Act
6 of 2023” or the “PASTEUR Act of 2023”.

1 **SEC. 2. DEVELOPING ANTIMICROBIAL INNOVATIONS.**

2 Title III of the Public Health Service Act (42 U.S.C.
3 241 et seq.) is amended by adding at the end the fol-
4 lowing:

5 **“PART W—DEVELOPING ANTIMICROBIAL**
6 **INNOVATIONS**

7 **“SEC. 3990O. ESTABLISHMENT OF COMMITTEE; SUBSCRIP-**
8 **TION MODEL; ADVISORY GROUP.**

9 “(a) IN GENERAL.—Not later than 60 days after the
10 date of enactment of this part, the Secretary shall estab-
11 lish a Committee on Critical Need Antimicrobials and ap-
12 point members to the Committee.

13 “(b) MEMBERS.—

14 “(1) IN GENERAL.—The Committee shall con-
15 sist of at least one representative from each of the
16 National Institute of Allergy and Infectious Dis-
17 eases, the Centers for Disease Control and Preven-
18 tion, the Biomedical Advanced Research and Devel-
19 opment Authority, the Food and Drug Administra-
20 tion, the Centers for Medicare & Medicaid Services,
21 the Veterans Health Administration, and the De-
22 partment of Defense.

23 “(2) CHAIR.—The Secretary shall appoint as
24 the Chair of the Committee a non-voting, inde-
25 pendent member who may not be a member of the

1 Committee or from an organization represented
2 under paragraph (1).

3 “(3) CONSULTATION.—The Secretary shall con-
4 sult with the Under Secretary of Veterans Affairs
5 for Health and Secretary of Defense when appoint-
6 ing members from the Veterans Health Administra-
7 tion and the Department of Defense.

8 “(c) DUTIES.—Not later than 1 year after the ap-
9 pointment of all initial members of the Committee, the
10 Secretary, in collaboration with the Committee, and in
11 consultation with the Critical Need Antimicrobials Advi-
12 sory Group established under subsection (g), shall do the
13 following:

14 “(1) Develop a list of infections for which new
15 antimicrobial drug development is needed, taking
16 into account organisms, sites of infection, and type
17 of infections for which there is an unmet medical
18 need, findings from the most recent report entitled
19 ‘Antibiotic Resistance Threats in the United States’
20 issued by the Centers for Disease Control and Pre-
21 vention, or an anticipated unmet medical need, in-
22 cluding a potential global health security threat. For
23 the list developed under this paragraph, the Sec-
24 retary, in collaboration with the Committee, may use
25 the infection list in such most recent Antibiotic Re-

1 sistance Threats in the United States report for up
2 to 3 years following the date of enactment of this
3 part and subsequently update the list under this
4 paragraph in accordance with subsection (e).

5 “(2) Develop regulations, for purposes of sub-
6 section (d), outlining favored characteristics of crit-
7 ical need antimicrobial drugs, that are evidence
8 based, clinically focused, and designed to treat the
9 infections described in paragraph (1), and estab-
10 lishing criteria for how each such characteristic or
11 combinations of multiple characteristics will adjust
12 the monetary value of a subscription contract award-
13 ed under subsection (f) or section 39900–2. The fa-
14 vored characteristics shall be weighed for purposes
15 of such monetary value of the subscription contract
16 such that meeting certain characteristics, or meeting
17 more than one such characteristic, increases the
18 monetary value of the subscription contract. Such
19 favored characteristics of an antimicrobial drug shall
20 include—

21 “(A) treating infections on the list under
22 paragraph (1);

23 “(B) improving clinical outcomes for pa-
24 tients with multi-drug-resistant infections;

1 “(C) being a first-approved antimicrobial
2 drug that has the potential to address, or has
3 the evidence of addressing, unmet medical
4 needs for the treatment of a serious or life-
5 threatening infection, and, to a lesser extent,
6 second and third drugs that treat such infec-
7 tions;

8 “(D) route of administration, especially
9 through oral administration;

10 “(E)(i) containing no active moiety (as de-
11 fined by the Secretary in section 314.3 of title
12 21, Code of Federal Regulations (or any suc-
13 cessor regulations)) that has been approved in
14 any other application under section 505(b) of
15 the Federal Food, Drug, and Cosmetic Act or
16 intending to be the subject of a new biological
17 product license application under section
18 351(a);

19 “(ii) being a member of a new class of
20 drugs with a novel target or novel mode of ac-
21 tion that are distinctly different from the target
22 or mode of any antimicrobial drug approved
23 under section 505 of such Act or licensed under
24 section 351, including reduced toxicity; or

1 “(iii) not being affected by cross-resistance
2 to any antimicrobial drug approved under such
3 section 505 or licensed under such section 351;

4 “(F) addressing a multi-drug resistant in-
5 fection through a novel chemical scaffold or
6 mechanism of action;

7 “(G) having received a transitional sub-
8 scription contract under subsection (f); and

9 “(H) any other characteristic the Com-
10 mittee or the Critical Need Antimicrobial Advi-
11 sory Group established under subsection (g) de-
12 termines necessary.

13 “(d) REGULATIONS.—

14 “(1) IN GENERAL.—Not later than 18 months
15 after the appointment of the initial members of the
16 Committee, the Secretary shall issue proposed regu-
17 lations which shall include—

18 “(A) a process by which the sponsors can
19 apply for an antimicrobial drug to become a
20 critical need antimicrobial drug under section
21 39900–1;

22 “(B) how subscription contracts under sec-
23 tion 39900–2 shall be established and paid;

24 “(C) the favored characteristics under sub-
25 section (c)(2), how such characteristics will be

1 weighed, and the minimum number and kind of
2 favored characteristics needed for an anti-
3 microbial drug to be designated a critical need
4 antimicrobial drug; and

5 “(D) other elements of the subscription
6 contract process, in accordance with this part.

7 “(2) DEVELOPMENT OF FINAL REGULA-
8 TIONS.—Before finalizing the regulations under
9 paragraph (1), the Secretary shall solicit public com-
10 ment and hold public meetings for the period begin-
11 ning on the date on which the proposed regulations
12 are issued and ending on the date that is 150 days
13 after such date of issuance. The Secretary shall fi-
14 nalize and publish such regulations not later than
15 150 days after the close of such period of public
16 comment and meetings.

17 “(3) COMMITTEE RECOMMENDATIONS.—In
18 issuing regulations under this subsection, the Sec-
19 retary shall consider the recommendations of the
20 Committee under subsection (c)(2).

21 “(e) LIST OF INFECTIONS.—The Secretary, in col-
22 laboration with the Committee, shall update the list of in-
23 fections under subsection (c)(1) at least every 2 years fol-
24 lowing the development of the initial list under that sub-
25 section.

1 “(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

2 “(1) IN GENERAL.—Not earlier than 30 days
3 after the date of enactment of this part and ending
4 on the date that the Secretary finalizes the regula-
5 tions under subsection (d), the Secretary may use up
6 to 10 percent of the amount appropriated under sec-
7 tion 39900–4(a) to engage in transitional subscrip-
8 tion contracts of up to 5 years in length with anti-
9 microbial developers, as determined by the Sec-
10 retary, that have developed antimicrobial drugs
11 treating infections listed in the most recent report
12 entitled ‘Antibiotic Resistance Threats in the United
13 States’ issued by the Centers for Disease Control
14 and Prevention, and may include antimicrobial drugs
15 that are qualified infectious disease products (as de-
16 fined in section 505E(g) of the Federal Food, Drug,
17 and Cosmetic Act), innovative biological products, or
18 innovative drugs that achieve improved clinical out-
19 comes. Such a contract may authorize the contractor
20 to use funds made available under the contract for
21 completion of postmarketing clinical studies, manu-
22 facturing, and other preclinical and clinical efforts.

23 “(2) REQUIREMENTS.—

24 “(A) IN GENERAL.—The Secretary,
25 through the office described in paragraph (4),

1 may enter into a contract under paragraph
2 (1)—

3 “(i) if the Secretary determines that
4 the antimicrobial drug is intended to treat
5 an infection for which there is an unmet
6 clinical need, an anticipated clinical need,
7 or drug resistance;

8 “(ii) subject to terms including—

9 “(I) that the Secretary shall
10 cease any payment installments under
11 a transitional subscription contract if
12 the sponsor does not—

13 “(aa) ensure commercial
14 availability of the antimicrobial
15 drug within 30 days of receiving
16 first payment under the contract;

17 “(bb) identify, track, and
18 publicly report drug resistance
19 data, and trends using available
20 data related to the antimicrobial
21 drug;

22 “(cc) develop and implement
23 education and communications
24 strategies, including communica-
25 tions for individuals with limited

1 English proficiency and individ-
2 uals with disabilities, for health
3 care professionals and patients
4 about appropriate use of the
5 antimicrobial drug;

6 “(dd) submit a plan for reg-
7 istering the antimicrobial drug in
8 additional countries where an
9 unmet medical need exists, which
10 such plan may be consistent with
11 the Stewardship and Access Plan
12 (SAP) Development Guide
13 (2021);

14 “(ee) subject to subpara-
15 graph (B), ensure a reliable drug
16 supply chain, thus leading to an
17 interruption of the supply of the
18 antimicrobial drug in the United
19 States for more than 60 days; or

20 “(ff) make meaningful
21 progress toward completion of
22 Food and Drug Administration-
23 required postmarketing studies,
24 including such studies that are
25 evidence based; and

1 “(II) other terms as determined
2 by the Secretary; and

3 “(iii) if—

4 “(I) a phase 3 clinical study has
5 been initiated for the antimicrobial
6 drug; or

7 “(II) the antimicrobial drug has
8 been approved under section 505(c) of
9 the Federal Food, Drug, and Cos-
10 metic Act or licensed under section
11 351(a).

12 “(B) WAIVER.—The requirement under
13 subparagraph (A)(ii)(I)(ee) may be waived in
14 the case that an emergency prohibits access to
15 a reliable drug supply chain.

16 “(3) TRANSITIONAL GUIDANCE.—Not later
17 than 120 days after the appointment of the initial
18 members of the Committee, the Secretary shall
19 issue, in consultation with the Committee, transi-
20 tional guidance outlining the characteristics of anti-
21 microbial drugs that are eligible for transitional sub-
22 scription contracts under paragraph (1), the require-
23 ments to enter into a transitional subscription con-
24 tract under paragraph (2), and the process by which
25 drug developers can enter into transitional subscrip-

1 tion contracts with the Secretary under this sub-
2 section.

3 “(4) PAYMENT OFFICE AND MECHANISM.—Not
4 later than 30 days after the date of enactment of
5 this part, the Secretary shall establish within the
6 Administration for Strategic Preparedness and Re-
7 sponse an office to manage the transitional subscrip-
8 tion contracts, including eligibility, requirements,
9 and contract amounts, during the period described
10 in paragraph (1).

11 “(g) CRITICAL NEED ANTIMICROBIAL ADVISORY
12 GROUP.—

13 “(1) IN GENERAL.—Not later than 30 days
14 after the appointment of all initial members of the
15 Committee, the Secretary, in collaboration with the
16 Committee, shall establish a Critical Need Anti-
17 microbial Advisory Group (referred to in this sub-
18 section as the ‘Advisory Group’) and appoint mem-
19 bers to the Advisory Group.

20 “(2) MEMBERS.—The members of the Advisory
21 Group shall include—

22 “(A) not fewer than 6 individuals who
23 are—

24 “(i) infectious disease specialists; or

1 “(ii) other health experts with exper-
2 tise in researching antimicrobial resistance,
3 health economics, or commercializing anti-
4 microbial drugs; and

5 “(B) not fewer than 5 patient advocates.

6 “(3) CHAIR.—The Secretary shall appoint as
7 Chair of the Advisory Group a non-voting, inde-
8 pendent member who may not be a member rep-
9 resented under paragraph (2).

10 “(4) CONFLICTS OF INTEREST.—In appointing
11 members under paragraph (2) and a Chair under
12 paragraph (3), the Secretary shall ensure that no
13 member receives compensation in any manner from
14 a commercial or for-profit entity that develops
15 antimicrobials or that might benefit from anti-
16 microbial development.

17 “(5) APPLICABILITY OF FACa.—Except as oth-
18 erwise provided in this subsection, the Federal Advi-
19 sory Committee Act shall apply to the Advisory
20 Group.

21 **“SEC. 39900-1. DESIGNATION OF ANTIMICROBIAL DRUG AS**
22 **CRITICAL NEED ANTIMICROBIAL DRUG.**

23 “(a) IN GENERAL.—

24 “(1) SUBMISSION OF REQUEST.—The sponsor
25 of an application under section 505(b) of the Fed-

1 eral Food, Drug, and Cosmetic Act or section 351(a)
2 for an antimicrobial drug may request that the Sec-
3 retary designate the drug as a critical need anti-
4 microbial. A request for such designation may be
5 submitted after the Secretary grants for such drug
6 an investigational new drug exemption under section
7 505(i) of the Federal Food, Drug, and Cosmetic Act
8 or section 351(a)(3), and shall be submitted not
9 later than 5 years after the date of approval under
10 section 505(c) of the Federal Food, Drug, and Cos-
11 metic Act or licensure under section 351(a).

12 “(2) CONTENT OF REQUEST.—A request under
13 paragraph (1) shall include information, such as
14 clinical, preclinical, and postmarketing data, a list of
15 the favorable characteristics described in section
16 39900(c)(2), and any other material that the Sec-
17 retary in consultation with the Committee requires.

18 “(3) REVIEW BY SECRETARY.—The Secretary
19 shall promptly review all requests for designation
20 submitted under this subsection, assess all required
21 application components, and determine if the anti-
22 microbial drug is likely to meet the favorable charac-
23 teristics identified in the application upon the com-
24 pletion of clinical development. After review, the Sec-
25 retary shall approve or deny each request for des-

1 ignation not later than 90 days after receiving a re-
2 quest. If the Secretary approves a request, it shall
3 publish the value of the contract that the critical
4 need antimicrobial developer would be eligible to re-
5 ceive if such developer successfully demonstrates
6 that the drug meets the maximum value of the fa-
7 vored characteristics listed in the application.

8 “(4) LENGTH OF DESIGNATION PERIOD.—A
9 designation granted under this section shall be in ef-
10 fect for a period of 10 years after the date that the
11 designation is approved, and shall remain in effect
12 for such period even if the infection treated by such
13 drug is later removed from the list of infections
14 under section 39900(c)(1).

15 “(5) SUBSEQUENT REVIEWS.—Not earlier than
16 2 years after a designation approval or denial under
17 paragraph (3), the sponsor may request a subse-
18 quent review to re-evaluate the value of a contract
19 to include any new information.

20 “(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a
21 critical need antimicrobial designation is granted during
22 clinical development of an antimicrobial drug, the Sec-
23 retary may work with the sponsor to maximize the oppor-
24 tunity for the sponsor to successfully demonstrate that the

1 antimicrobial drug possesses the favored characteristics
2 identified under section 39900(c)(2).

3 “(c) APPROPRIATE USE OF CRITICAL NEED ANTI-
4 MICROBIAL.—

5 “(1) IN GENERAL.—The sponsor of an anti-
6 microbial drug that receives designation under sub-
7 section (a) shall, within 90 days of such designation,
8 submit to the Secretary a plan for appropriate use
9 of diagnostics, in order for the Secretary and Com-
10 mittee to consider such plan in developing clinical
11 guidelines. An appropriate use plan—

12 “(A) shall include—

13 “(i) the appropriate use of the drug;

14 and

15 “(ii) the appropriate use of diagnostic
16 tools, where available, or a plan to coordi-
17 nate development of diagnostic tools as
18 necessary; and

19 “(B) may be developed in partnership with
20 the Secretary, infectious disease experts, diag-
21 nostic experts or developers, laboratory experts,
22 or another entity.

23 “(2) CONSULTATION.—The Secretary shall con-
24 sult with relevant professional societies and the Crit-
25 ical Need Antimicrobial Advisory Group established

1 under section 39900(g) to ensure that clinical
2 guidelines issued by the Secretary under paragraph
3 (3), with respect to an antimicrobial drug designated
4 under subsection (a), includes the use of appropriate
5 diagnostic approaches, taking into consideration the
6 diagnostic plan submitted by a sponsor under para-
7 graph (1).

8 **“SEC. 39900-2. ESTABLISHMENT OF SUBSCRIPTION CON-**
9 **TRACT OFFICE; SUBSCRIPTION CONTRACTS.**

10 “(a) SUBSCRIPTION CONTRACT OFFICE.—

11 “(1) IN GENERAL.—Not later than 180 days
12 after the date of enactment of this part, the Sec-
13 retary shall establish within the Administration for
14 Strategic Preparedness and Response an office, to
15 be known as the ‘Subscription Contract Office’, the
16 head of which shall be the Director (referred to in
17 this section as the ‘Director’).

18 “(2) PURPOSE.—The purpose of the Office es-
19 tablished under paragraph (1) shall be to manage
20 the establishment and payment of subscription con-
21 tracts awarded under this section, including eligi-
22 bility, requirements, and contract amounts.

23 “(b) APPLICATION FOR A SUBSCRIPTION CON-
24 TRACT.—

1 “(1) SUBMISSION OF APPLICATIONS.—After ap-
2 proval under section 505(c) of the Federal Food,
3 Drug, and Cosmetic Act or licensure under section
4 351(a), the sponsor of an antimicrobial drug des-
5 ignated as a critical need antimicrobial under section
6 39900–1 may submit an application for a subscrip-
7 tion contract to the Director, under a procedure es-
8 tablished by the Director.

9 “(2) REVIEW OF APPLICATIONS.—The Director,
10 in consultation with the Committee, shall—

11 “(A) review all applications for subscrip-
12 tion contracts under paragraph (1) and assess
13 all required application components;

14 “(B) determine the extent to which the
15 critical need antimicrobial drug covered by the
16 application meets the favored characteristics
17 identified under section 39900(e)(2); and

18 “(C) deny any application for a drug that
19 does not meet the minimum number and kind
20 of favored characteristics needed for the drug to
21 be designated as a critical need antimicrobial
22 based on the regulations issue under section
23 39900(d).

24 “(c) REQUIREMENTS.—As a condition of entering
25 into a subscription contract under this section, the sponsor

1 of the critical need antimicrobial drug covered by the ap-
2 plication shall agree to—

3 “(1) ensure commercial availability of the anti-
4 microbial drug within 30 days of receiving first pay-
5 ment under the contract, and sufficient supply for
6 susceptibility device manufacturers;

7 “(2) identify, track, and publicly report drug
8 resistance data, and trends using available data re-
9 lated to the antimicrobial drug;

10 “(3) develop and implement education and com-
11 munications strategies, including communications
12 for individuals with limited English proficiency and
13 individuals with disabilities, for health care profes-
14 sionals and patients about appropriate use of the
15 antimicrobial drug;

16 “(4) submit an appropriate use assessment to
17 the Secretary, the Committee, the Administrator of
18 the Food and Drug Administration, and the Director
19 of the Centers for Disease Control and Prevention
20 every 2 years regarding use of the antimicrobial
21 drug, including how the drug is being marketed;

22 “(5) submit a plan for registering the drug in
23 additional countries where an unmet medical need
24 exists;

1 “(6) ensure a reliable drug supply chain, where
2 any interruption to the supply chain will not last for
3 more than 60 days in the United States;

4 “(7) complete any postmarketing studies re-
5 quired by the Food and Drug Administration in a
6 timely manner;

7 “(8) produce the drug at a reasonable volume
8 determined with the Director to ensure patient ac-
9 cess to the drug;

10 “(9) abide by the manufacturing and environ-
11 mental best practices in the supply chain for the
12 control of discharge of antimicrobial active pharma-
13 ceutical ingredients to ensure minimal discharge
14 into, or contamination of, the environment by anti-
15 microbial agents or products as a result of the man-
16 ufacturing process; and

17 “(10) abide by such other terms as the Director
18 may require.

19 “(d) MONETARY VALUE.—

20 “(1) IN GENERAL.—The Director, in consulta-
21 tion with the Committee, shall assign a monetary
22 value to each subscription contract under this sec-
23 tion based on the regulations developed under sec-
24 tion 39900(d).

1 “(2) CONSIDERATIONS.—In assigning a mone-
2 tary value to a subscription contract under para-
3 graph (1), the Director shall take into account the
4 favored characteristic or combination of favored
5 characteristics of the drug covered by the contract,
6 as determined by the Director, in consultation with
7 the Committee, under subsection (b)(2)(B).

8 “(e) AMOUNT OF CONTRACTS.—

9 “(1) IN GENERAL.—A subscription contract
10 under this section shall be for the sale to the Sec-
11 retary of any quantity of the antimicrobial drug cov-
12 ered by the contract needed over the term of the
13 contract, at a price agreed on by the sponsor and
14 the Director, based on the monetary value assigned
15 to the contract under subsection (d).

16 “(2) MINIMUM AND MAXIMUM AMOUNT.—The
17 total projected amount to be paid by the Director
18 under a subscription contract under this section
19 shall be not less than \$750,000,000 and not more
20 than \$3,000,000,000, adjusted for inflation.

21 “(f) TERM.—

22 “(1) INITIAL TERM.—The initial term of a sub-
23 scription contract under this section shall be—

24 “(A) not less than 5 years; and

25 “(B) not greater than the greater of—

1 “(i) 10 years; and

2 “(ii) the remaining period of time dur-
3 ing which the sponsor has patent protec-
4 tions or a remaining exclusivity period with
5 respect to the antimicrobial drug in the
6 United States, as listed in the publication
7 of the Food and Drug Administration enti-
8 tled ‘Approved Drug Products with Thera-
9 peutic Equivalence Evaluations’.

10 “(2) EFFECT.—A subscription contract shall
11 remain in effect for the period described in para-
12 graph (1) even if the infection treated by the anti-
13 microbial drug covered by the subscription contract
14 is later removed from the list of infections under
15 section 39900(c)(1).

16 “(3) EXTENSION OF CONTRACTS.—The Direc-
17 tor may extend a subscription contract with a spon-
18 sor under this subsection beyond the initial contract
19 period. A single contract extension may be in effect
20 not later than the date on which all periods of exclu-
21 sivity granted by the Food and Drug Administration
22 expire and shall be in an amount not to exceed
23 \$25,000,000 per year. All other terms of an ex-
24 tended contract shall be the same as the terms of
25 the initial contract. The total amount of funding

1 used on such contract extensions shall be no more
2 than \$1,000,000,000, and shall be allocated from
3 the amount made available under section 39900–
4 4(a).

5 “(4) MODIFICATION OF CONTRACTS.—The Di-
6 rector or sponsor, 1 year after the start of the con-
7 tract period under this subsection and every 2 years
8 thereafter, may request a modification of the
9 amount of the contract based on information that
10 adjusts favored characteristics in section
11 39900(e)(2).

12 “(g) PAYMENTS.—

13 “(1) IN GENERAL.—Not later than 180 days
14 after the date on which a subscription contract is
15 granted under subsection (a), the Director shall pro-
16 vide payments for drugs purchased under the con-
17 tract in installments established by the Director, in
18 consultation with the sponsor of the antimicrobial
19 drug and in accordance with subsection (j).

20 “(2) TIMING OF PAYMENTS.—The Director—

21 “(A) may make payments under paragraph
22 (1) in equal annual installments; and

23 “(B) shall not make such payments more
24 frequently than twice per year.

1 “(3) OPTION.—The sponsor shall have the op-
2 tion to receive 50 percent of the payment amount
3 due in the last year of the contract during the first
4 year of the contract in order to offset costs of estab-
5 lishing manufacturing capacity.

6 “(4) FUNDING.—Payments under this sub-
7 section shall be allocated from the amount made
8 available under section 39900–4(a).

9 “(5) ADJUSTMENT.—In the case of an anti-
10 microbial drug that received a transitional subscrip-
11 tion contract under section 39900(f), the amount of
12 a subscription contract for such drug under this sec-
13 tion shall be reduced by the amount of the transi-
14 tional subscription contract under such section
15 39900(f) for such drug.

16 “(h) USE OF CONTRACT FUNDS.—Funds received by
17 the sponsor under a subscription contract under this sec-
18 tion shall be used—

19 “(1) to meet the requirements described in sub-
20 section (c); and

21 “(2) to support the completion of post-
22 marketing clinical studies, manufacturing, other pre-
23 clinical and clinical activities, or other activities
24 agreed to by the Director and sponsor in the con-
25 tract.

1 “(i) CONTRACTS FOR GENERIC AND BIOSIMILAR
2 VERSIONS.—Notwithstanding any other provision of this
3 part, the Director may award a subscription contract
4 under this section to a manufacturer of a generic or bio-
5 similar version of an antimicrobial drug for which a sub-
6 scription contract has been awarded under this section.
7 Such contracts shall be awarded in accordance with a pro-
8 cedure, including for determining the terms and amounts
9 of such contracts, established by the Director.

10 “(j) ANTIMICROBIAL DRUG SPONSOR REVENUE LIM-
11 ITATIONS.—

12 “(1) REQUIREMENT.—

13 “(A) IN GENERAL.—With respect to a pay-
14 ment installment under a subscription contract
15 entered into under this section, the net revenue
16 from sales of the applicable antimicrobial drug
17 for beneficiaries or enrollees in Federal health
18 care programs during the period covered by the
19 payment installment shall be subtracted from
20 the payment installment.

21 “(B) PAYMENT.—The amount calculated
22 under subparagraph (A) shall be paid by the
23 Secretary to the relevant Federal health care
24 program (or its trust fund) at the time of the
25 applicable installment payment.

1 “(C) COORDINATION.—The Director shall
2 coordinate with the relevant agencies of the
3 Federal Government, including the Centers for
4 Medicare and Medicaid Services, to carry out
5 this subsection in a manner that ensures mini-
6 mal disruption to how a health care provider
7 currently acquires applicable antimicrobial
8 drugs.

9 “(2) REGULATIONS.—

10 “(A) IN GENERAL.—To carry out this sub-
11 section, the Secretary shall promulgate regula-
12 tions to identify the Federal health care pro-
13 grams applicable under this section, including
14 Medicare part A and Medicaid, and to establish
15 the methodology and data collection require-
16 ments necessary to calculate the amount under
17 paragraph (1)(A).

18 “(B) METHODOLOGY.—Any methodology
19 established for the collection of data and cal-
20 culation of the amount under paragraph (1)(A)
21 shall take into account any legally mandated or
22 voluntary discounts and rebates provided by the
23 manufacturer of the applicable antimicrobial
24 drug to the Federal health care programs that
25 pay for such drug, on the condition that the

1 Secretary may presume that discounts not de-
2 scribed in subclauses (I) and (II) of subpara-
3 graph (C)(ii) are captured in the price deter-
4 mined under subparagraph (C)(i)(II).

5 “(C) ESTIMATING ANNUAL NET REV-
6 ENUE.—

7 “(i) IN GENERAL.—In determining
8 the net revenue from sales of the applica-
9 ble antimicrobial drug for beneficiaries or
10 enrollees in Federal health care programs
11 for the purpose of calculating the amount
12 under paragraph (1)(A), the Secretary
13 shall determine such net revenue amount
14 by multiplying—

15 “(I) the total number of billing
16 units of such antimicrobial drugs re-
17 ported under the process described in
18 subparagraph (D)(ii) for the applica-
19 ble payment installment period; by

20 “(II) the average sales price (as
21 defined in section 1847A(c) of the So-
22 cial Security Act), the average manu-
23 facturer price (as defined in section
24 1927(k)(1) of the Social Security
25 Act), or another pricing metric used

1 in Federal health care programs, for
2 such antimicrobial drugs.

3 “(ii) REQUIREMENT.—The Secretary
4 shall adjust the amount determined under
5 clause (i)(II) to account for—

6 “(I) rebates, discounts, add-on
7 payments, or other adjustments pro-
8 vided under—

9 “(aa) section 340B; or

10 “(bb) section 1927 of the
11 Social Security Act; or

12 “(II) negotiated price concessions
13 described in section 1860D-
14 2(d)(1)(B) of the Social Security Act
15 that are not captured in the applicable
16 price.

17 “(D) CODING.—

18 “(i) IN GENERAL.—In promulgating
19 regulations under subparagraph (A), the
20 Secretary shall, as appropriate, establish
21 and assign codes, under existing or new
22 coding systems, to identify units of the ap-
23 plicable antimicrobial drug for beneficiaries
24 or enrollees in Federal health care pro-
25 grams.

1 “(ii) CODING USE REQUIREMENTS.—

2 In promulgating regulations under sub-
3 paragraph (A), the Secretary shall require
4 hospitals (or other providers or suppliers)
5 that administer applicable antimicrobial
6 drugs in the inpatient or outpatient setting
7 to report on their claims to such Federal
8 health care programs the billing units of
9 such antimicrobial drugs used in the care
10 of beneficiaries or enrollees in each Federal
11 health care program, regardless of whether
12 payment for those units are separately re-
13 imbursed.

14 “(3) DEFINITIONS.—In this subsection:

15 “(A) APPLICABLE ANTIMICROBIAL
16 DRUG.—The term ‘applicable antimicrobial
17 drug’ means an antimicrobial drug for which
18 the sponsor of such drug receives a subscription
19 contract under subsection (a).

20 “(B) FEDERAL HEALTH CARE PROGRAM.—

21 The term ‘Federal health care program’ has the
22 meaning given such term in section 1128B(f) of
23 the Social Security Act, except that, for pur-
24 poses of this subsection, such term includes the

1 health insurance program under chapter 89 of
2 title 5, United States Code.

3 “(k) FAILURE TO ADHERE TO TERMS.—The Sec-
4 retary shall cease any payment installments under a con-
5 tract under this section if—

6 “(1) the sponsor—

7 “(A) permanently withdraws the anti-
8 microbial drug from the market in the United
9 States;

10 “(B) fails to meet the requirements de-
11 scribed in subsection (c); or

12 “(C) does not complete a postmarket study
13 required by the Food and Drug Administration
14 during the term of the contract;

15 “(2) the annual international and private insur-
16 ance market revenues with respect to an anti-
17 microbial drug (not counting any subscription reve-
18 nues from any source pursuant to a contract under
19 this section or other international or private entities)
20 exceed 5 times the average annual amount of the
21 subscription contract paid by the Secretary as cer-
22 tified by the sponsor annually; or

23 “(3) if the total revenue of the sponsor from
24 government programs that pay for drugs subject to
25 a contract agreement entered into pursuant to this

1 section for a year exceeds the amount of the sub-
2 scription contract paid by the Secretary for that
3 year.

4 “(l) PRIVATE PAYER AND INTERNATIONAL PAYER
5 PARTICIPATION.—The Secretary shall make efforts to in-
6 crease the participation of domestic private payors and
7 international payors in subscription contracts or other
8 types of value-based arrangements that are similar to the
9 subscription contracts authorized under this section.

10 “(m) EFFECT.—Nothing in this section permits the
11 Secretary to use evidence from comparative clinical effec-
12 tiveness research in a manner that treats extending the
13 life of an elderly, disabled, or terminally ill individual as
14 of lower value than extending the life of an individual who
15 is younger, nondisabled, or not terminally ill in deter-
16 mining the value of an antimicrobial drug or a subscrip-
17 tion contract (or a transitional subscription contract), in-
18 cluding in such a way that would limit patient access.

19 **“SEC. 39900-3. ENCOURAGING APPROPRIATE USE OF**
20 **ANTIMICROBIALS AND COMBATING RESIST-**
21 **ANCE.**

22 “(a) ESTABLISHMENT OF HEALTH FACILITY GRANT
23 PROGRAM.—

24 “(1) IN GENERAL.—Not later than 1 year after
25 the date of enactment of this part, the Secretary

1 shall establish a grant program under the Centers
2 for Disease Control and Prevention to support hos-
3 pital, skilled nursing facility, and other health care
4 facility efforts—

5 “(A) to judiciously use antimicrobial drugs,
6 such as by establishing or implementing appro-
7 priate use programs, including infectious dis-
8 ease telehealth programs, using appropriate di-
9 agnostic tools, partnering with academic hos-
10 pitals, increasing health care-associated infec-
11 tion reporting and prevention efforts, and moni-
12 toring antimicrobial resistance; and

13 “(B) to participate in the National
14 Healthcare Safety Network Antimicrobial Use
15 and Resistance Module or the Emerging Infec-
16 tions Program Healthcare-Associated Infections
17 Community Interface activity of the Centers for
18 Disease Control and Prevention or a similar re-
19 porting program, as specified by the Secretary,
20 relating to antimicrobial drugs.

21 “(2) PRIORITIZATION.—In awarding grants
22 under paragraph (1), the Secretary shall prioritize
23 health care facilities without an existing program to
24 judiciously use antimicrobial drugs, subsection (d)
25 hospitals (as defined in subparagraph (B) of section

1 1886(d)(2) of the Social Security Act that are lo-
2 cated in rural areas (as defined in subparagraph (D)
3 of such section), critical access hospitals (as defined
4 in section 1861(mm)(1) of such Act), hospitals serv-
5 ing Tribal populations, and safety-net hospitals.

6 “(b) SURVEILLANCE AND REPORTING OF ANTI-
7 MICROBIAL USE AND RESISTANCE.—

8 “(1) IN GENERAL.—The Secretary, acting
9 through the Director of the Centers for Disease
10 Control and Prevention, shall use the National
11 Healthcare Safety Network and other appropriate
12 surveillance systems to assess trends in antimicrobial
13 resistance and antibiotic and antifungal use, such
14 as—

15 “(A) appropriate conditions and measures
16 causally related to antimicrobial resistance, in-
17 cluding types of infections, the source or body
18 sites of infections, the demographic information
19 of patients with infections, and infection onset
20 in a community or hospital setting, increased
21 lengths of hospital stay, increased costs, and
22 rates of mortality; and

23 “(B) changes in bacterial and fungal re-
24 sistance to antimicrobial drugs, including
25 changes in percent resistance, prevalence of

1 antimicrobial-resistant infections, rates of mor-
2 tality, and other such changes.

3 “(2) ANTIMICROBIAL USE DATA.—The Sec-
4 retary, acting through the Director of the Centers
5 for Disease Control and Prevention, shall obtain reli-
6 able and comparable human antibiotic and
7 antifungal drug consumption data (including, as
8 available and appropriate, volume antimicrobial dis-
9 tribution data and antibiotic and antifungal use
10 data, including prescription data) by State or metro-
11 politan areas. To accomplish this, the Centers for
12 Disease Control and Prevention may work with, as
13 appropriate, Federal departments and agencies (in-
14 cluding the Department of Veterans Affairs, the De-
15 partment of Defense, the Department of Homeland
16 Security, the Bureau of Prisons, the Indian Health
17 Service, and the Centers for Medicare & Medicaid
18 Services), private vendors, health care organizations,
19 pharmacy benefit managers, and other entities.

20 “(3) ANTIMICROBIAL RESISTANCE TREND
21 DATA.—The Secretary, acting through the Director
22 of the Centers for Disease Control and Prevention,
23 shall intensify and expand efforts to collect anti-
24 microbial resistance data and encourage adoption of
25 the Antibiotic Use and Resistance Module within the

1 National Healthcare Safety Network among all
2 health care facilities across the continuum of care,
3 including, as appropriate, acute care hospitals, dialy-
4 sis facilities, nursing homes, ambulatory surgical
5 centers, and other ambulatory health care settings in
6 which antimicrobial drugs are routinely prescribed.
7 The Secretary shall seek to collect such data from
8 electronic medication administration reports and lab-
9 oratory systems to produce the reports described in
10 paragraph (4).

11 “(4) PUBLIC AVAILABILITY OF DATA.—Begin-
12 ning on the date that is 2 years after the date of
13 enactment of this part, the Secretary, acting
14 through the Director of the Centers for Disease
15 Control and Prevention, shall, for the purposes of
16 improving the monitoring of important trends in
17 antimicrobial use and resistance, and, as appro-
18 priate, patient outcomes in relation to antimicrobial
19 resistance—

20 “(A) make the data described under this
21 subsection publicly available through reports
22 and web updates issued on a regular basis that
23 is not less than annually; and

24 “(B) examine opportunities to make such
25 data available in near real time.

1 “(c) PUBLICATION OF CLINICAL GUIDELINES.—Not
2 later than 1 year after the date the Secretary makes the
3 first designation under section 39900–1(a), and not less
4 than every 3 years thereafter, the Secretary shall publish
5 at least one update to clinical guidelines in consultation
6 with relevant professional societies. As appropriate, guide-
7 line updates shall include each antimicrobial drug that has
8 been approved under section 505(c) of the Federal Food,
9 Drug, and Cosmetic Act or licensed under section 351(a)
10 and that has been designated under section 39900–1(a),
11 which guidelines shall set forth the evidence-based rec-
12 ommendations for prescribing the drug for the relevant in-
13 fection time, in accordance with the available evidence
14 after consultation under section 39900-1(c)(2), as appro-
15 priate.

16 “(d) FUNDING.—The Secretary may use not more
17 than 5 percent of the amounts appropriated under section
18 39900–4(a) to carry out this section.

19 **“SEC. 39900–4. APPROPRIATIONS.**

20 “(a) IN GENERAL.—To carry out this part, there are
21 hereby appropriated to the Secretary, out of amounts in
22 the Treasury not otherwise appropriated, \$6,000,000,000
23 for fiscal year 2024, to remain available until expended.

24 “(b) EMERGENCY DESIGNATION.—

1 “(1) IN GENERAL.—The amounts provided by
2 this section are designated as an emergency require-
3 ment pursuant to section 4(g) of the Statutory Pay-
4 As-You-Go Act of 2010.

5 “(2) DESIGNATION IN SENATE.—In the Senate,
6 this section is designated as an emergency require-
7 ment pursuant to section 4112(a) of H. Con. Res.
8 71 (115th Congress), the concurrent resolution on
9 the budget for fiscal year 2018.

10 **“SEC. 39900-5. STUDIES AND REPORTS.**

11 “(a) IN GENERAL.—Not later than 6 years after the
12 date of enactment of this part, the Comptroller General
13 of the United States shall complete a study on the effec-
14 tiveness of this part in developing priority antimicrobial
15 drugs. Such study shall examine the indications for, usage
16 of, development of resistance with respect to, and private
17 and societal value of critical need antimicrobial drugs, and
18 the impact of the programs under this part on markets
19 of critical need antimicrobial drugs. The Comptroller Gen-
20 eral shall report to the Committee on Health, Education,
21 Labor, and Pensions of the Senate and the Committee on
22 Energy and Commerce of the House of Representatives
23 on the findings of such study.

24 “(b) ANTIBIOTIC USE IN THE UNITED STATES; AN-
25 NUAL REPORTS.—The Director of the Centers for Disease

1 Control and Prevention shall, each year, update the report
2 entitled ‘Antibiotic Use in the United States’ to include
3 updated information on progress and opportunities with
4 respect to data, programs, and resources for prescribers
5 to promote appropriate use of antimicrobial drugs.

6 “(c) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—
7 Not later than 3 years after the date of enactment of this
8 part, the Director of the Centers for Disease Control and
9 Prevention shall publish a report on antimicrobial prophyl-
10 lactics.

11 **“SEC. 39900-6. DEFINITIONS.**

12 “In this part—

13 “(1) the term ‘antimicrobial drug’—

14 “(A) means, subject to subparagraph (B),
15 a product that is—

16 “(i) a drug that directly inhibits rep-
17 lication of or kills bacteria or fungi, or acts
18 on the substances produced by such bac-
19 teria or fungi, relevant to the proposed in-
20 dication at concentrations likely to be at-
21 tainable in humans to achieve the intended
22 therapeutic effect; or

23 “(ii) a biological product that acts di-
24 rectly on bacteria or fungi or on the sub-

1 stances produced by such bacteria or fungi;

2 and

3 “(B) does not include—

4 “(i) a drug that achieves the effect de-
5 scribed by subparagraph (A)(i) only at a
6 concentration that cannot reasonably be
7 studied in humans because of its antici-
8 pated toxicity; or

9 “(ii) a vaccine; and

10 “(2) the term ‘Committee’ means the Com-
11 mittee on Critical Need Antimicrobials established
12 under section 39900(a).”.

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