

116TH CONGRESS
2D SESSION

H. R. 8920

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

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 9, 2020

Mr. MICHAEL F. DOYLE of Pennsylvania (for himself and Mr. FERGUSON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Veterans' Affairs, Armed Services, the Judiciary, Homeland Security, and Natural Resources, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

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 Up surging Resistance
6 Act of 2020” or “The PASTEUR Act”.

1 **SEC. 2. ESTABLISHMENT OF COMMITTEE; SUBSCRIPTION**

2 **MODEL; ADVISORY GROUP.**

3 (a) IN GENERAL.—Not later than 60 days after the
4 date of enactment of this Act, the Secretary shall establish
5 a Committee on Critical Need Antimicrobials and appoint
6 members to the Committee.

7 (b) MEMBERS.—

8 (1) IN GENERAL.—The Committee shall consist
9 of at least one representative from each of the Na-
10 tional Institute of Allergy and Infectious Diseases,
11 the Centers for Disease Control and Prevention, the
12 Biomedical Advanced Research and Development
13 Authority, the Food and Drug Administration, the
14 Centers for Medicare & Medicaid Services, the Vet-
15 erans Health Administration, and the Department of
16 Defense.

17 (2) CHAIR.—The Secretary shall appoint one of
18 the members of the Committee to serve as the Chair
19 of the Committee.

20 (c) DUTIES.—Not later than 1 year after the appoint-
21 ment of all initial members of the Committee, the Sec-
22 retary, in collaboration with the Committee, and in con-
23 sultation with the Critical Need Antimicrobials Advisory
24 Group established under subsection (g), shall do the fol-
25 lowing:

1 (1) Develop a list of prioritized infections for
2 which new antimicrobial drug development is needed,
3 taking into account infections for which there is an
4 unmet medical need, findings from the most recent
5 report entitled “Antibiotic Resistance Threats in the
6 United States” issued by the Centers for Disease
7 Control and Prevention, or an anticipated unmet
8 medical need. For the list developed under this para-
9 graph, the Secretary, in collaboration with the Com-
10 mittee, may use the infection list in such most re-
11 cent report for up to 3 years following the date of
12 enactment of this Act and subsequently update the
13 list under this paragraph in accordance with sub-
14 section (e).

15 (2) Develop regulations, in accordance with
16 subsection (d), outlining favored characteristics of
17 critical need antimicrobial drugs, that are evidence
18 based, clinically focused, and designed to treat the
19 infections described in paragraph (1), and estab-
20 lishing criteria for how each such characteristic will
21 adjust the monetary value of a subscription contract
22 awarded under subsection (f) or section 4. The fa-
23 vored characteristics shall be weighed for purposes
24 of such monetary value such that meeting certain
25 characteristics, or meeting more than one such char-

acteristic, increases the monetary value. Such favored characteristics of an antimicrobial drug shall include—

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

(B) improving clinical outcomes for patients with multi-drug resistant infections;

(C) being a first-approved drug that treats certain multi-drug resistant infections, and, to a lesser extent, second and third drugs that treat such infections;

(D) addressing an infection located in an organ or other location that is challenging to treat;

(E) addressing a multi-drug resistant infection through a novel chemical scaffold or mechanism of action, especially through oral administration;

(F) having received a transitional subscription contract under subsection (f); and

(G) any other characteristic the Secretary, in collaboration with the Committee, determines necessary.

(d) REGULATIONS.—

1 (1) IN GENERAL.—Not later than 1 year after
2 the appointment of the initial members of the Com-
3 mittee, the Secretary shall issue proposed regula-
4 tions which shall include—

5 (A) a process by which the sponsors can
6 apply for an antimicrobial drug to become a
7 critical need antimicrobial drug under section 3;

8 (B) how subscription contracts under such
9 section shall be established and paid;

10 (C) the favored characteristics under sub-
11 section (c)(2), how such characteristics will be
12 weighed, and the minimum number and kind of
13 favored characteristics needed for an anti-
14 microbial drug to be designated a critical need
15 antimicrobial drug; and

16 (D) other elements of the subscription con-
17 tract process, in accordance with this Act.

18 (2) DEVELOPMENT OF FINAL REGULATIONS.—
19 Before finalizing the regulations under paragraph
20 (1), the Secretary shall solicit public comment and
21 hold public meetings for the period beginning on the
22 date on which the proposed regulations are issued
23 and ending on the date that is 120 days after such
24 date of issuance, and shall finalize and publish the

1 regulations 60 days after the close of such period of
2 public comment and meetings.

3 (3) SUBSCRIPTION CONTRACT OFFICE.—Not
4 later than 6 months after the date of enactment of
5 this Act, the Secretary shall propose an agency or
6 office in the Department of Health and Human
7 Services to manage the establishment and payment
8 of subscription contracts awarded under section 4,
9 including eligibility, requirements, and contract
10 amounts. The Secretary shall solicit public comment
11 and finalize the agency or office no later than 45
12 days following the proposed agency or office.

13 (e) LIST OF INFECTIONS.—The Secretary, in collabo-
14 ration with the Committee, shall update the list of infec-
15 tions under subsection (c)(1) at least every 2 years.

16 (f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

17 (1) IN GENERAL.—Not earlier than 30 days
18 after the date of enactment of this Act and ending
19 on the date that the Secretary finalizes the subscrip-
20 tion contract regulations under subsection (d), the
21 Secretary may use up to \$1,000,000,000 of the
22 amount appropriated under section 6(a) to engage in
23 transitional subscription contracts of up to 3 years
24 in length with antimicrobial developers, as deter-
25 mined by the Secretary, that have developed anti-

1 microbial drugs treating infections listed in the most
2 recent report entitled “Antibiotic Resistance Threats
3 in the United States” issued by the Centers for Dis-
4 ease Control and Prevention, and may include anti-
5 microbial drugs that are qualified infectious disease
6 products (as defined in section 505E(g) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 355f(g))), similarly innovative biologic antimicrobial
9 drugs, or innovative drugs that achieve an anti-
10 microbial outcome through immunomodulation.
11 Funds made available under such contracts may be
12 used for a variety of purposes including to support
13 the completion of postmarketing clinical studies,
14 manufacturing, and other preclinical and clinical ef-
15 forts.

16 (2) REQUIREMENTS.—

17 (A) IN GENERAL.—The Secretary, through
18 the office described in paragraph (4), may enter
19 into a contract under paragraph (1)—

20 (i) if the Secretary determines that
21 the antimicrobial drug demonstrates a sig-
22 nificant clinical advancement in treating an
23 infection for which there is an unmet clin-
24 ical need, an anticipated clinical need, or
25 multidrug resistance;

1 (ii) subject to terms including—

2 (I) that the Secretary shall cease
3 any payment installments under a
4 transitional subscription contract if
5 the sponsor does not—

6 (aa) ensure commercial and
7 Federal availability of the anti-
8 microbial drug within 30 days of
9 receiving first payment under the
10 contract;

11 (bb) identify, track, and
12 publicly report drug resistance
13 data and trends using available
14 data related to the antimicrobial
15 drug;

16 (cc) develop and implement
17 education and communications
18 strategies, including communica-
19 tions for individuals with limited
20 English proficiency and individ-
21 uals with disabilities, for health
22 care professionals and patients
23 about appropriate use of the
24 antimicrobial drug;

(dd) submit a plan for registering the antimicrobial drug in additional countries where an unmet medical need exists;

(ee) subject to subparagraph (B), ensure a reliable drug supply chain, thus leading to an interruption of the supply of the antimicrobial drug in the United States for more than 60 days; or

(ff) make meaningful progress toward completion of Federal Drug Administration-required postmarketing studies, including such studies that are evidence based; and

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

(iii) if—

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

(II) the antimicrobial drug has been approved under section 505(c) of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 355(c)) or li-
2 censed under section 351(a) of the
3 Public Health Service Act (42 U.S.C.
4 262(a)).

5 (B) WAIVER.—The requirement under sub-
6 paragraph (A)(ii)(I)(ee) may be waived in the
7 case that an emergency prohibits access to a re-
8 liable drug supply chain.

9 (3) TRANSITIONAL GUIDANCE.—Not later than
10 30 days after the appointment of the initial mem-
11 bers of the Committee, the Secretary shall issue, in
12 consultation with the Committee, transitional guid-
13 ance outlining the antimicrobial drugs that are eligi-
14 ble for transitional subscription contracts under
15 paragraph (1), the requirements to enter into a
16 transitional subscription contract under paragraph
17 (2), and the process by which drug developers can
18 enter into transitional subscription contracts with
19 the Secretary under this subsection.

20 (4) PAYMENT OFFICE AND MECHANISM.—Not
21 later than 30 days after the date of enactment of
22 this Act, the Secretary shall determine the agency or
23 office in the Department of Health and Human
24 Services that will manage the transitional subscrip-
25 tion contracts, including eligibility, requirements,

1 and contract amounts, during the period described
2 in paragraph (1).

3 (g) CRITICAL NEED ANTIMICROBIAL ADVISORY
4 GROUP.—

5 (1) IN GENERAL.—Not later than 30 days after
6 the appointment of all initial members of the Com-
7 mittee, the Secretary, in collaboration with the Com-
8 mittee, shall establish a Critical Need Antimicrobial
9 Advisory Group (referred to in this subsection as the
10 “Advisory Group”) and appoint members to the Ad-
11 visory Group.

12 (2) MEMBERS.—The members of the Advisory
13 Group shall include—

14 (A) 6 individuals who are—

15 (i) infectious disease specialists; or

16 (ii) other health experts with expertise
17 in researching antimicrobial resistance,
18 health economics, or commercializing anti-
19 microbial drugs; and

20 (B) not less than 5 patient advocates.

21 (3) CHAIR.—The Secretary shall appoint one of
22 the members of the Advisory Group to serve as the
23 Chair.

24 (4) CONFLICTS OF INTEREST.—In appointing
25 members under paragraph (2), the Secretary shall

1 ensure that no member receives compensation in any
2 manner from a commercial or for-profit entity that
3 develops antimicrobials or that might benefit from
4 antimicrobial development.

5 (5) APPLICABILITY OF FACA.—Except as other-
6 wise provided in this subsection, the Federal Advi-
7 sory Committee Act (5 U.S.C. App.) shall apply to
8 the Advisory Group.

9 **SEC. 3. CRITICAL NEED ANTIMICROBIAL DRUG APPLICA-**
10 **TION AND PAYMENT THROUGH SUBSCRIP-**
11 **TION CONTRACTS.**

12 (a) IN GENERAL.—

13 (1) SUBMISSION OF REQUEST.—The sponsor of
14 an application under section 505(b) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 355(b))
16 or section 351(a) of the Public Health Service Act
17 (42 U.S.C. 262(a)) for an antimicrobial drug may
18 request that the Secretary designate the drug as a
19 critical need antimicrobial. A request for such des-
20 ignation may be submitted after the Secretary
21 grants for such drug an investigational new drug ex-
22 emption under section 505(i) of the Federal Food,
23 Drug, and Cosmetic Act or section 351(a)(3) of the
24 Public Health Service Act, and shall be submitted
25 not later than 5 years after the date of approval

1 under section 505(c) of the Federal Food, Drug, and
2 Cosmetic Act or licensure under section 351(a) of
3 the Public Health Service Act.

4 (2) CONTENT OF REQUEST.—A request under
5 paragraph (1) shall include information, such as
6 clinical, preclinical and postmarketing data, a list of
7 the favorable characteristics described in section
8 2(c)(2), and any other material that the Secretary in
9 consultation with the Committee requires.

10 (3) REVIEW BY SECRETARY.—The Secretary
11 shall promptly review all requests for designation
12 submitted under this subsection, assess all required
13 application components, and determine if the anti-
14 microbial drug is likely to meet the favorable charac-
15 teristics identified in the application upon the com-
16 pletion of clinical development. After review, the Sec-
17 retary shall approve or deny each request for des-
18 ignation no later than 90 days after receiving a re-
19 quest. If the Secretary approves a request, it shall
20 publish the value of the contract that the critical
21 need antimicrobial developer would be eligible to re-
22 ceive if such developer successfully demonstrates
23 that the drug meets the maximum value of the fa-
24 vored characteristics listed in the application.

1 (4) LENGTH OF DESIGNATION PERIOD.—A des-
2 ignation granted under this section shall be in effect
3 for a period of 10 years after the date that the des-
4 ignation is approved, and shall remain in effect for
5 such period even if the infection treated by such
6 drug is later removed from the list of infections
7 under section 2(c)(1).

8 (5) SUBSEQUENT REVIEWS.—No sooner than 2
9 years after a designation approval or denial under
10 subsection (3), the sponsor may request a subse-
11 quent review to re-evaluate the value of a contract
12 to include any new information.

13 (b) DEVELOPMENT OF DESIGNATED DRUGS.—If a
14 critical need antimicrobial designation is granted during
15 clinical development of an antimicrobial drug, the Sec-
16 retary may work with the sponsor to maximize the oppor-
17 tunity for the sponsor to successfully demonstrate that the
18 antimicrobial drug possesses the favored characteristics of
19 high-monetary valued products identified under section
20 2(c)(2).

21 (c) APPROPRIATE USE OF CRITICAL NEED ANTI-
22 MICROBIAL.—

23 (1) IN GENERAL.—The sponsor of an anti-
24 microbial drug that receives designation under sub-
25 section (a) shall submit an appropriate use plan to

1 the Secretary within 90 days of application approval
2 for appropriate use of diagnostics for consideration
3 by the Secretary and Committee to develop clinical
4 guidelines. A diagnostic plan—

5 (A) shall include—

6 (i) the appropriate use of the drug;

7 and

8 (ii) the appropriate use of diagnostic
9 tools such as diagnostic testing for bio-
10 markers related to antimicrobial-resistant
11 pathogens, or other targeted diagnostic ap-
12 proaches, to inform use of the drug; and

13 (B) may be developed in partnership with
14 the Secretary, infectious disease experts, diag-
15 nostic experts, or another entity.

16 (2) CONSULTATION.—The Secretary shall work
17 with relevant professional societies and the Critical
18 Need Antimicrobial Advisory Group established
19 under section 2(g) to ensure that clinical guidelines
20 issued by the Secretary under paragraph (3), with
21 respect to an antimicrobial drug designated under
22 subsection (a), includes the use of appropriate diag-
23 nostic approaches, taking into consideration the di-
24 agnostic plan submitted by a sponsor under para-
25 graph (1).

1 (3) PUBLICATION OF CLINICAL GUIDELINES.—

2 Not later than 1 year after the Secretary makes the
3 first designation under subsection (a), and not less
4 than every 3 years thereafter, the Secretary shall
5 publish clinical guidelines in collaboration with rel-
6 evant professional societies with respect to each anti-
7 microbial drug designated under subsection (a)
8 which shall set forth the evidence-based rec-
9 ommendations for prescribing the drug, in accord-
10 ance with the submissions of the sponsor under
11 paragraph (1) and after consultation under para-
12 graph (2), as appropriate.

13 **SEC. 4. SUBSCRIPTION CONTRACTS.**

14 (a) APPLICATION FOR A SUBSCRIPTION CON-
15 TRACT.—

16 (1) SUBMISSION OF APPLICATIONS.—After ap-
17 proval under section 505(c) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 355(c)) or licen-
19 sure under section 351(a) of the Public Health Serv-
20 ice Act (42 U.S.C. 262(a)), the sponsor of an anti-
21 microbial drug designated as a critical need anti-
22 microbial under section 3 may submit an application
23 for a subscription contract with the Secretary, under
24 a procedure established by the Secretary.

1 (2) REVIEW OF APPLICATIONS.—The Secretary
2 shall, in consultation with the Committee—

3 (A) review all applications for subscription
4 contracts under paragraph (1) and assess all
5 required application components;

6 (B) determine the extent to which the crit-
7 ical need antimicrobial meets the favored char-
8 acteristics identified under section 2(c)(2), and
9 deny any application for a drug that meets
10 none of such characteristics; and

11 (C) assign a monetary value to the con-
12 tract based on the regulations developed under
13 section 2(d).

14 (b) CRITERIA.—To qualify for a subscription contract
15 under this section, the sponsor of an antimicrobial drug
16 designated as a critical need antimicrobial shall agree to—

17 (1) ensure commercial and Federal availability
18 of the antimicrobial drug within 30 days of receiving
19 first payment under the contract, and sufficient sup-
20 ply for susceptibility device manufacturers;

21 (2) identify, track, and publicly report drug re-
22 sistance data and trends using available data related
23 to the antimicrobial drug;

24 (3) develop and implement education and com-
25 munications strategies, including communications

1 for individuals with limited English proficiency and
2 individuals with disabilities, for health care profes-
3 sionals and patients about appropriate use of the
4 antimicrobial drug;

5 (4) submit an appropriate use assessment to
6 the Secretary, Committee, Food and Drug Adminis-
7 tration, and Centers for Disease Control and Pre-
8 vention every 2 years regarding use of the anti-
9 microbial drug, including how the drug is being mar-
10 keted;

11 (5) submit a plan for registering the drug in
12 additional countries where an unmet medical need
13 exists;

14 (6) ensure a reliable drug supply chain, where
15 any interruption to the supply chain will not last for
16 more than 60 days in the United States;

17 (7) complete any postmarketing studies re-
18 quired by the Food and Drug Administration in a
19 timely manner;

20 (8) produce the drug at a reasonable volume de-
21 termined with the Secretary to ensure patient access
22 to the drug;

23 (9) price the drug at a price that is not lower
24 than a comparable generic drug; and

1 (10) abide by other terms as the Secretary may
2 require.

3 (c) TERM AND AMOUNT OF CONTRACTS.—

4 (1) AMOUNTS.—A subscription contract under
5 this section shall be for the sale to the Secretary of
6 any quantity of the antimicrobial drug needed over
7 the term of the contract under paragraph (2), at an
8 agreed upon price, for a total projected amount de-
9 termined by the Secretary that is not less than
10 \$750,000,000 and not more than \$3,000,000,000,
11 adjusted for inflation, accounting for the favored
12 characteristics of the drug, as determined by the
13 Secretary, in consultation with the Committee, under
14 subsection (a)(2), and shall be allocated from the
15 amount made available under section 6(a). Not later
16 than 6 months after the subscription contract is
17 granted under subsection (a), the Secretary shall
18 provide payments for purchased drugs in install-
19 ments established by the Secretary in consultation
20 with the sponsor of the antimicrobial drug and in ac-
21 cordance with subsection (d)(3). Funds received by
22 the sponsor may be used to support criteria quali-
23 fication under subsection (b), the completion of post-
24 marketing clinical studies, manufacturing, and other

preclinical and clinical activities agreed to by the Secretary and sponsor in the contract.

(2) TERMS.—

(A) INITIAL TERM.—The initial term of a contract under this subsection shall be no less than 5 years or greater than the greater of 10 years or the remaining period of time during which the sponsor has patent protections or a remaining exclusivity period with respect to the antimicrobial drug in the United States, as listed in the publication of the Food and Drug Administration entitled “Approved Drug Products with Therapeutic Equivalence Evaluations”. Payments may be in equal annual installments with the option to redeem 50 percent of the last year’s reimbursement in year 1 of the contract in order to offset costs of establishing manufacturing capacity, or another subscription arrangement to which the Secretary and sponsor agree. Subscription contracts shall remain in effect for such period even if the infection treated by such antimicrobial drug is later removed from the list of infections under section 2(c)(1).

(B) EXTENSION OF CONTRACTS.—The Secretary may extend subscription contracts be-

1 yond the initial contract period with a generic
2 or biosimilar brand manufacturer of the anti-
3 microbial drug receiving a subscription contract
4 or the original drug manufacturer. A single
5 contract extension may be in effect not later
6 than the date on which all periods of exclusivity
7 granted by the Food and Drug Administration
8 expire and shall be in an amount not to exceed
9 \$25,000,000 per year. All other terms of an ex-
10 tended contract shall be the same as the terms
11 of the initial contract. The total amount of
12 funding used on such contract extensions shall
13 be no more than \$1,000,000,000, and shall be
14 allocated from the amount made available under
15 section 6.

16 (C) MODIFICATION OF CONTRACTS.—The
17 Secretary or sponsor, every 2 years after the
18 start of the contract period under this sub-
19 section, may request a modification of the
20 amount of the contract based on information
21 that adjusts favored characteristics in section
22 2(c)(2).

23 (3) ADJUSTMENT.—In the case of an anti-
24 microbial drug that received a transitional subscrip-
25 tion contract under section 2(f), the amount of a

1 subscription contract for such drug under this sec-
2 tion shall be reduced by the amount of the transi-
3 tional subscription contract under such section 2(f)
4 for such drug.

5 (d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REV-
6 ENUE LIMITATIONS.—

7 (1) REPORTING REQUIREMENT.—

8 (A) IN GENERAL.—Not later than a date
9 determined appropriate by the Secretary fol-
10 lowing the end of each calendar year, the head
11 (or a designee of such head) of each Federal
12 agency carrying out a specified government pro-
13 gram shall, in accordance with this paragraph,
14 report to the Secretary of Health and Human
15 Services the total prescription drug sales for
16 each applicable antimicrobial drug under con-
17 tract with respect to such program for such cal-
18 endar year.

19 (B) MEDICARE PART D PROGRAM.—For
20 purposes of subparagraph (A), the Secretary
21 shall report, for each applicable antimicrobial
22 drug covered under part D of title XVIII of the
23 Social Security Act (42 U.S.C. 1395w–101 et
24 seq.), the product of—

1 (i) the per-unit ingredient cost, as re-
2 ported to the Secretary by prescription
3 drug plans and Medicare Advantage pre-
4 scription drug plans, minus any per-unit
5 rebate, discount, or other price concession
6 provided, as reported to the Secretary by
7 the prescription drug plans and the Medi-
8 care Advantage prescription drug plans;
9 and

10 (ii) the number of units of such appli-
11 cable antimicrobial drug paid for under
12 such part D.

13 (C) MEDICARE PART B PROGRAM.—For
14 purposes of subparagraph (A), the Secretary
15 shall report, for each applicable antimicrobial
16 drug covered under part B of title XVIII of the
17 Social Security Act (42 U.S.C. 1395j et seq.),
18 the product of—

19 (i) the per-unit average sales price (as
20 defined in section 1847A(c) of such Act
21 (42 U.S.C. 1395w–3a(c))) or the per-unit
22 payment rate under such part B for a sep-
23 arately paid prescription drug without a
24 reported average sales price; and

1 (ii) the number of units of such appli-
2 cable antimicrobial drug paid for under
3 such part B.

4 (D) MEDICARE PART A PROGRAM.—

5 (i) IN GENERAL.—For purposes of
6 subparagraph (A), the Secretary shall re-
7 port, for each applicable antimicrobial drug
8 covered under part A of title XVIII of the
9 Social Security Act (42 U.S.C. 1395c et
10 seq.), the product of—

11 (I) the per-unit price under such
12 part A for the antimicrobial drug; and

13 (II) the number of units of such
14 antimicrobial drug paid for under
15 such part A.

16 (ii) SPECIAL RULE.—For purposes of
17 clause (i), the Secretary shall establish a
18 process for determining the units and the
19 allocated price for those prescription drugs
20 that are not separately payable or for
21 which National Drug Codes are not re-
22 ported in the diagnosis-related groups.

23 (E) MEDICAID PROGRAM.—Under the au-
24 thority of section 1902(a)(6) of the Social Secu-
25 rity Act (42 U.S.C. 1396a(a)(6)), the Secretary

1 shall require each State that makes medical as-
2 sistance available under the State Medicaid pro-
3 gram for an applicable antimicrobial drug (in-
4 cluding, if applicable, any such drug which is a
5 covered outpatient drug under a rebate agree-
6 ment entered into under section 1927 of such
7 Act (42 U.S.C. 1396r-8)) to report to the Sec-
8 retary, not later than the date established
9 under subparagraph (A), for each dosage form
10 and strength and package size of each such
11 drug dispensed during the preceding calendar
12 year under the State Medicaid program, the
13 amount equal to—

14 (i) the product of—

15 (I) the per-unit ingredient cost
16 paid by the State for each such drug;
17 and

18 (II) the number of units of such
19 drug paid for under the State Med-
20 icaid program; minus

21 (ii) any discounts or other price con-
22 cessions provided and rebates paid to the
23 State with respect to such drug and such
24 calendar year (including rebates paid
25 under a rebate agreement under section

1 1927 of such Act (42 U.S.C. 1396r–8) and
2 any State supplemental rebates paid under
3 a supplemental rebate agreement).

4 (F) DEPARTMENT OF VETERANS AF-
5 FAIRS.—For purposes of subparagraph (A), the
6 Secretary of Veterans Affairs shall report the
7 total amount paid for each applicable anti-
8 microbial drug procured by the Veterans Health
9 Administration for individuals who receive
10 health care from the Administration.

11 (G) DEPARTMENT OF DEFENSE AND
12 TRICARE PROGRAM.—For purposes of subpara-
13 graph (A), the Secretary of Defense shall report
14 the sum of—

15 (i) the total amount paid for each ap-
16 plicable antimicrobial drug procured by the
17 Department of Defense for individuals who
18 receive health care from the Department;
19 and

20 (ii) for each applicable antimicrobial
21 drug dispensed under the TRICARE retail
22 pharmacy program, the product of—

23 (I) the per-unit ingredient cost,
24 minus any per-unit rebate paid by the
25 covered entity; and

1 (II) the number of units of such
2 applicable antimicrobial drug dis-
3 pensed under such program.

4 (H) DEPARTMENT OF HOMELAND SECUR-
5 RITY.—For purposes of subparagraph (A), the
6 Secretary of Homeland Security shall report the
7 total amount paid for each applicable anti-
8 microbial drug procured by the Department of
9 Homeland Security for individuals who receive
10 health care through a program carried out by
11 the Department.

12 (I) BUREAU OF PRISONS.—For purposes of
13 subparagraph (A), the Director of the Bureau
14 of Prisons shall report the total amount paid
15 for each applicable antimicrobial drug procured
16 by the Bureau of Prisons for individuals who
17 receive health care through the Bureau.

18 (J) INDIAN HEALTH SERVICE.—For pur-
19 poses of subparagraph (A), the Secretary, act-
20 ing through the Indian Health Service, shall re-
21 port the total amount paid for each applicable
22 antimicrobial drug procured by the Service for
23 individuals who receive health care through the
24 Service.

1 (2) GUIDANCE.—Not later than 1 year after
2 the date of enactment of this Act, the Secretary
3 shall publish guidance to assist the heads (or des-
4 ignees) of Federal agencies carrying out specified
5 government programs in carrying out the require-
6 ments under this section.

7 (3) SUBSCRIPTION CONTRACT ADJUSTMENT.—
8 Pursuant to the contract entered into under this sec-
9 tion with respect to an applicable antimicrobial drug,
10 for each year of the term of such contract, the Sec-
11 retary shall subtract from the payment installments
12 determined for such contract under subsection (c)(1)
13 for such year the revenue of the sponsor of such
14 drug from the previous year from sales of the appli-
15 cable antimicrobial drug reported under paragraph
16 (1) for specified government programs.

17 (4) DEFINITIONS.—In this subsection:

18 (A) APPLICABLE ANTIMICROBIAL DRUG.—

19 The term “applicable antimicrobial drug”
20 means an antimicrobial drug for which the
21 sponsor of such drug receives a subscription
22 contract under subsection (a).

23 (B) SPECIFIED GOVERNMENT PROGRAM.—

24 The term “specified government program”
25 means—

1 (i) the Medicare part D program
2 under part D of title XVIII of the Social
3 Security Act (42 U.S.C. 1395w–101 et
4 seq.);

5 (ii) the Medicare Part B program
6 under part B of such title XVIII (42
7 U.S.C. 1395j et seq.);

8 (iii) the Medicare Part A program
9 under part A of such title XVIII (42
10 U.S.C. 1395c et seq.);

11 (iv) the Medicaid program established
12 under title XIX of the Social Security Act
13 (42 U.S.C. 1396 et seq.) and includes,
14 with respect to a State, any waiver in ef-
15 fect with respect to such program;

16 (v) any program under which pre-
17 scription drugs are procured by the De-
18 partment of Veterans Affairs;

19 (vi) any program under which brand-
20 ed prescription drugs are procured by the
21 Department of Defense;

22 (vii) the TRICARE retail pharmacy
23 program under section 1074g of title 10,
24 United States Code;

1 (viii) any program under which pre-
2 scription drugs are procured by the De-
3 partment of Homeland Security;

4 (ix) any program under which pre-
5 scription drugs are procured by the Bu-
6 reau of Prisons; or

7 (x) any program under which pre-
8 scription drugs are procured by the Indian
9 Health Service.

10 (e) FAILURE TO ADHERE TO TERMS.—The Sec-
11 retary shall cease any payment installments under a con-
12 tract under this section if—

13 (1) the sponsor—

14 (A) permanently withdraws the anti-
15 microbial drug from the market in the United
16 States;

17 (B) fails to meet criteria under subsection
18 (b); or

19 (C) does not complete a postmarket study
20 required by the Food and Drug Administration
21 during the length of the term of the contract;
22 or

23 (2) the annual international and private insur-
24 ance market revenues with respect to an anti-
25 microbial drug (not counting any subscription reve-

1 nues from any source pursuant to a contract under
 2 this section or other international or private entities)
 3 exceed 5 times the average annual amount of the
 4 subscription contract paid by the Secretary as cer-
 5 tified by the sponsor annually.

6 (f) PRIVATE PAYER AND INTERNATIONAL PAYER
 7 PARTICIPATION.—The Secretary shall make efforts to in-
 8 crease the participation of domestic private payors and
 9 international payors in subscription contracts or other
 10 types of pull incentives that are similar to the subscription
 11 contracts authorized under this section.

12 **SEC. 5. ENCOURAGING APPROPRIATE USE OF ANTIBIOTICS**
 13 **AND COMBATING RESISTANCE.**

14 (a) ESTABLISHMENT OF HOSPITAL GRANT PRO-
 15 GRAM.—

16 (1) IN GENERAL.—Not later than 1 year after
 17 the date of enactment of this Act, the Secretary and
 18 the Director of the Centers for Disease Control and
 19 Prevention shall coordinate with the Administrator
 20 of the Health Resources and Services Administra-
 21 tion, the Administrator of the Centers for Medicare
 22 & Medicaid Services, the National Coordinator for
 23 Health Information Technology, and other relevant
 24 agencies, to establish a grant program under the

Centers for Disease Control and Prevention to support hospital and other inpatient facility efforts—

(A) to judiciously use antimicrobial drugs, such as by establishing or implementing appropriate use programs, including infectious disease telehealth programs, using appropriate diagnostic tools, partnering with academic hospitals, increasing health care-associated infection reporting, and monitoring antimicrobial resistance; and

(B) to participate in the National Healthcare Safety Network Antimicrobial Use and Resistance Module or the Emerging Infections Program Healthcare-Associated Infections Community Interface activity of the Centers for Disease Control and Prevention or a similar reporting program, as specified by the Secretary, relating to antimicrobial drugs.

(2) PRIORITIZATION.—In awarding grants under paragraph (1), the Secretary shall prioritize hospitals without an existing program to judiciously use antimicrobial drugs, subsection (d) hospitals (as defined in subparagraph (B) of section 1886(d)(2) of the Social Security Act (42 U.S.C. 1395ww(d)(2))) that are located in rural areas (as

1 defined in subparagraph (D) of such section), crit-
2 ical access hospitals (as defined in section
3 1861(mm)(1) of such Act (42 U.S.C.
4 1395x(mm)(1))), hospitals serving Tribal-popu-
5 lations, and safety-net hospitals.

6 (3) FUNDING.—Of the amounts appropriated
7 under section 6, the Secretary shall reserve
8 \$500,000,000 to carry out this subsection.

9 (b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC
10 USE AND RESISTANCE.—

11 (1) IN GENERAL.—The Secretary, acting
12 through the Director of the Centers for Disease
13 Control and Prevention, shall use the National
14 Healthcare Safety Network and other appropriate
15 surveillance systems to assess—

16 (A) appropriate conditions, outcomes, and
17 measures causally related to antibacterial resist-
18 ance, including types of infections, the causes
19 for infections, and whether infections are ac-
20 quired in a community or hospital setting, in-
21 creased lengths of hospital stay, increased costs,
22 and rates of mortality; and

23 (B) changes in bacterial resistance to anti-
24 microbial drugs in relation to patient outcomes,
25 including changes in percent resistance, preva-

1 lence of antibiotic-resistant infections, and other
2 such changes.

3 (2) ANTIBIOTIC USE DATA.—The Secretary,
4 acting through the Director of the Centers for Dis-
5 ease Control and Prevention, shall work with Fed-
6 eral agencies (including the Department of Veterans
7 Affairs, the Department of Defense, the Department
8 of Homeland Security, the Bureau of Prisons, the
9 Indian Health Service, and the Centers for Medicare
10 & Medicaid Services), private vendors, health care
11 organizations, pharmacy benefit managers, and
12 other entities as appropriate to obtain reliable and
13 comparable human antibiotic drug consumption data
14 (including, as available and appropriate, volume an-
15 tibiotic distribution data and antibiotic use data, in-
16 cluding prescription data) by State or metropolitan
17 areas.

18 (3) ANTIBIOTIC RESISTANCE TREND DATA.—
19 The Secretary, acting through the Director of the
20 Centers for Disease Control and Prevention, shall in-
21 tensify and expand efforts to collect antibiotic resist-
22 ance data and encourage adoption of the antibiotic
23 resistance and use module within the National
24 Healthcare Safety Network among all health care fa-
25 cilities across the continuum of care, including, as

1 appropriate, acute care hospitals, dialysis facilities,
2 nursing homes, ambulatory surgical centers, and
3 other ambulatory health care settings in which anti-
4 microbial drugs are routinely prescribed. The Sec-
5 retary shall seek to collect such data from electronic
6 medication administration reports and laboratory
7 systems to produce the reports described in para-
8 graph (4).

9 (4) PUBLIC AVAILABILITY OF DATA.—The Sec-
10 retary, acting through the Director of the Centers
11 for Disease Control and Prevention, shall, for the
12 purposes of improving the monitoring of important
13 trends in patient outcomes in relation to anti-
14 bacterial resistance—

15 (A) make the data derived from surveil-
16 lance under this subsection publicly available
17 through reports issued on a regular basis that
18 is not less than annually; and

19 (B) examine opportunities to make such
20 data available in near real time.

21 **SEC. 6. APPROPRIATIONS.**

22 (a) IN GENERAL.—To carry out this Act, there are
23 hereby appropriated to the Secretary, out of amounts in
24 the Treasury not otherwise appropriated,

1 \$11,000,000,000, for fiscal year 2021, to remain available
2 until expended.

3 (b) EMERGENCY DESIGNATION.—

4 (1) IN GENERAL.—The amounts provided by
5 this section are designated as an emergency require-
6 ment pursuant to section 4(g) of the Statutory Pay-
7 As-You-Go Act of 2010 (2 U.S.C. 933(g)).

8 (2) DESIGNATION IN SENATE.—In the Senate,
9 this section is designated as an emergency require-
10 ment pursuant to section 4112(a) of H. Con. Res.
11 71 (115th Congress), the concurrent resolution on
12 the budget for fiscal year 2018.

13 **SEC. 7. STUDIES AND REPORTS.**

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

1 the Committee on Energy and Commerce of the House
2 of Representatives on the findings of such study.

3 (b) ANTIBIOTIC USE IN THE UNITED STATES; AN-
4 NUAL REPORTS.—The Director of the Centers for Disease
5 Control and Prevention shall, each year, update the report
6 entitled “Antibiotic Use in the United States” to include
7 updated information on progress and opportunities with
8 respect to data, programs, and resources for prescribers
9 to promote appropriate use of antimicrobial drugs.

10 (c) REPORTS ON ANTIFUNGAL RESISTANCE AND
11 ANTIMICROBIAL PROPHYLACTICS.—Not later than 3 years
12 after the date of enactment of this Act, the Director of
13 the Centers for Disease Control and Prevention shall pub-
14 lish—

15 (1) a report on antifungal resistance in the
16 United States; and

17 (2) a report on antimicrobial prophylactics.

18 **SEC. 8. DEFINITIONS.**

19 In this Act—

20 (1) the term “antimicrobial drug”—

21 (A) subject to subparagraph (B), means—

22 (i) an antibiotic drug, as defined in
23 section 201(jj) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 321(jj)); or

1 (ii) a biological product, as defined in
2 section 351(i) of the Public Health Service
3 Act (42 U.S.C. 262(i)), that exhibits anti-
4 microbial activity; and

5 (B) excludes—

6 (i) any antifungal drug; and

7 (ii) any vaccine;

8 (2) the term “Committee” means the Com-
9 mittee on Critical Need Antimicrobials established
10 under section 2; and

11 (3) the term “Secretary” means the Secretary
12 of Health and Human Services.

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