

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 2076

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

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 2022” or the “PASTEUR Act”.

7 **SEC. 2. DEVELOPING ANTIMICROBIAL INNOVATIONS.**

8 Title III of the Public Health Service Act (42 U.S.C.
9 241 et seq.) is amended by adding at the end the fol-
10 lowing:

1 sory Group established under subsection (g), shall do the
2 following:

3 “(1) Develop a list of infections and patient
4 types for which new antimicrobial drug development
5 is needed, taking into account patient factors, orga-
6 nisms, sites of infection, and type of infections for
7 which there is an unmet medical need, findings from
8 the most recent report entitled ‘Antibiotic Resistance
9 Threats in the United States’ issued by the Centers
10 for Disease Control and Prevention, or an antici-
11 pated unmet medical need, including a potential
12 global health security threat. For the list developed
13 under this paragraph, the Secretary, in collaboration
14 with the Committee, may use the infection list in
15 such most recent report for up to 3 years following
16 the date of enactment of this part and subsequently
17 update the list under this paragraph in accordance
18 with subsection (e).

19 “(2) Develop regulations, in accordance with
20 subsection (d), outlining favored characteristics of
21 critical need antimicrobial drugs, that are evidence
22 based, clinically focused, and designed to improve
23 patient outcomes in treating the infections described
24 in paragraph (1), and establishing criteria for how
25 each such characteristic or combinations of multiple

1 characteristics will adjust the monetary value of a
2 subscription contract awarded under subsection (f)
3 or section 39900–2. The favored characteristics
4 shall be weighed for purposes of such monetary
5 value such that meeting certain characteristics, or
6 meeting more than one such characteristic, increases
7 the monetary value. Such favored characteristics of
8 an antimicrobial drug shall include—

9 “(A) treating infections and patients on
10 the list under paragraph (1);

11 “(B) improving clinical and patient out-
12 comes for patients with multi-drug-resistant in-
13 fections;

14 “(C) being a first-approved antimicrobial
15 drug that has the evidence of addressing unmet
16 medical needs for the treatment of a serious or
17 life-threatening infection, and, to a lesser ex-
18 tent, second and third drugs that treat such in-
19 fections;

20 “(D) route of administration, especially
21 through oral administration;

22 “(E)(i) containing no active moiety (as de-
23 fined by the Secretary in section 314.3 of title
24 21, Code of Federal Regulations (or any suc-
25 cessor regulations)) that has been approved in

1 any other application under section 505(b) of
2 the Federal Food, Drug, and Cosmetic Act or
3 intending to be the subject of a new biological
4 product license application under section
5 351(a);

6 “(ii) being a member of a new class of
7 drugs with a novel target and novel mode of ac-
8 tion that are distinctly different from the target
9 or mode of any antimicrobial drug approved
10 under section 505 of such Act or licensed under
11 section 351, including reduced toxicity;

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

15 “(F) improving patient outcomes for an in-
16 fection through a novel chemical scaffold or
17 mechanism of action;

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

20 “(H) any other characteristic the Sec-
21 retary, in collaboration with the Committee, de-
22 termines necessary.

23 “(d) REGULATIONS.—

24 “(1) IN GENERAL.—Not later than 1 year after
25 the appointment of the initial members of the Com-

1 mittee, the Secretary shall issue proposed regula-
2 tions which shall include—

3 “(A) a process by which the sponsors can
4 apply for an antimicrobial drug to become a
5 critical need antimicrobial drug under section
6 39900–1;

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

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

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

17 “(2) DEVELOPMENT OF FINAL REGULA-
18 TIONS.—Before finalizing the regulations under
19 paragraph (1), the Secretary shall solicit public com-
20 ment and hold public meetings for the period begin-
21 ning on the date on which the proposed regulations
22 are issued and ending on the date that is 120 days
23 after such date of issuance. The Secretary shall fi-
24 nalize and publish such regulations not later than

1 120 days after the close of such period of public
2 comment and meetings.

3 “(3) SUBSCRIPTION CONTRACT OFFICE.—Not
4 later than 6 months after the date of enactment of
5 this part, 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
9 39900–2, including eligibility, requirements, and
10 contract amounts. The Secretary shall solicit public
11 comment and finalize the agency or office no later
12 than 45 days following the proposed agency or of-
13 fice. Such agency or office shall be referred to as the
14 ‘Subscription Contract Office’.

15 “(e) LIST OF INFECTIONS AND PATIENT TYPES.—
16 The Secretary, in collaboration with the Committee, shall
17 update the list of infections and patient types under sub-
18 section (c)(1) at least every 2 years.

19 “(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—
20 “(1) IN GENERAL.—Not earlier than 30 days
21 after the date of enactment of this part and ending
22 on the date that the Secretary finalizes the subscrip-
23 tion contract regulations under subsection (d), the
24 Secretary may use up to \$1,000,000,000 of the
25 amount appropriated under section 39900–4(a) to

1 engage in transitional subscription contracts of up to
2 3 years in length with antimicrobial developers, as
3 determined by the Secretary, that have developed
4 antimicrobial drugs treating infections listed in the
5 most recent report entitled ‘Antibiotic Resistance
6 Threats in the United States’ issued by the Centers
7 for Disease Control and Prevention, and may include
8 antimicrobial drugs that are qualified infectious dis-
9 ease products (as defined in section 505E(g) of the
10 Federal Food, Drug, and Cosmetic Act), innovative
11 biological products, or innovative drugs that achieve
12 improved clinical and patient outcomes through
13 immunomodulation. Such a contract may authorize
14 the contractor to use funds made available under the
15 contract for completion of postmarketing clinical
16 studies, manufacturing, and other preclinical and
17 clinical efforts.

18 “(2) REQUIREMENTS.—

19 “(A) IN GENERAL.—The Secretary,
20 through the office described in paragraph (4),
21 may enter into a contract under paragraph
22 (1)—

23 “(i) if the Secretary determines that
24 the antimicrobial drug is intended to treat
25 an infection and improves patient outcomes

1 for which there is an unmet clinical need,
2 an anticipated clinical need, or drug resist-
3 ance;

4 “(ii) subject to terms including—

5 “(I) that the Secretary shall
6 cease any payment installments under
7 a transitional subscription contract if
8 the sponsor does not—

9 “(aa) ensure commercial and
10 Federal availability of the anti-
11 microbial drug within 30 days of
12 receiving first payment under the
13 contract;

14 “(bb) identify, track, and
15 publicly report drug resistance
16 data, patient outcomes, and
17 trends using available data re-
18 lated to the antimicrobial drug;

19 “(cc) develop and implement
20 education and communications
21 strategies, including communica-
22 tions for individuals with limited
23 English proficiency and individ-
24 uals with disabilities, for health
25 care professionals and patients

1 about appropriate use of the
2 antimicrobial drug;

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

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

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

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

25 “(iii) if—

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

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

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

13 “(3) TRANSITIONAL GUIDANCE.—Not later
14 than 120 days after the appointment of the initial
15 members of the Committee, the Secretary shall
16 issue, in consultation with the Committee, transi-
17 tional guidance outlining the antimicrobial drugs
18 that are eligible for transitional subscription con-
19 tracts under paragraph (1), the requirements to
20 enter into a transitional subscription contract under
21 paragraph (2), and the process by which drug devel-
22 opers can enter into transitional subscription con-
23 tracts with the Secretary under this subsection.

24 “(4) PAYMENT OFFICE AND MECHANISM.—Not
25 later than 30 days after the date of enactment of

1 “(3) CHAIR.—The Secretary shall appoint one
2 of the members of the Advisory Group to serve as
3 the Chair.

4 “(4) CONFLICTS OF INTEREST.—In appointing
5 members under paragraph (2), the Secretary shall
6 ensure that no member receives compensation in any
7 manner from a commercial or for-profit entity that
8 develops antimicrobials or that might benefit from
9 antimicrobial development.

10 “(5) APPLICABILITY OF FACa.—Except as oth-
11 erwise provided in this subsection, the Federal Advi-
12 sory Committee Act shall apply to the Advisory
13 Group.

14 **“SEC. 3990-1. CRITICAL NEED ANTIMICROBIAL DRUG AP-**
15 **PLICATION AND PAYMENT THROUGH SUB-**
16 **SCRIPTION CONTRACTS.**

17 “(a) IN GENERAL.—

18 “(1) SUBMISSION OF REQUEST.—The sponsor
19 of an application under section 505(b) of the Fed-
20 eral Food, Drug, and Cosmetic Act or section 351(a)
21 for an antimicrobial drug may request that the Sec-
22 retary designate the drug as a critical need anti-
23 microbial. A request for such designation may be
24 submitted after the Secretary grants for such drug
25 an investigational new drug exemption under section

1 505(i) of the Federal Food, Drug, and Cosmetic Act
2 or section 351(a)(3), and shall be submitted not
3 later than 5 years after the date of approval under
4 section 505(c) of the Federal Food, Drug, and Cos-
5 metic Act or licensure under section 351(a).

6 “(2) CONTENT OF REQUEST.—A request under
7 paragraph (1) shall include information, such as
8 clinical, preclinical and postmarketing data, evidence
9 of patient outcomes, a list of the favorable charac-
10 teristics described in section 39900(c)(2), and any
11 other material that the Secretary in consultation
12 with the Committee requires.

13 “(3) REVIEW BY SECRETARY.—The Secretary
14 shall promptly review all requests for designation
15 submitted under this subsection, assess all required
16 application components, and determine if the anti-
17 microbial drug is likely to meet the favorable charac-
18 teristics identified in the application upon the com-
19 pletion of clinical development. After review, the Sec-
20 retary shall approve or deny each request for des-
21 ignation not later than 90 days after receiving a re-
22 quest. If the Secretary approves a request, it shall
23 publish the value of the contract that the critical
24 need antimicrobial developer would be eligible to re-
25 ceive if such developer successfully demonstrates

1 that the drug meets the maximum value of the fa-
2 vored characteristics listed in the application.

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

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

15 “(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a
16 critical need antimicrobial designation is granted during
17 clinical development of an antimicrobial drug, the Sec-
18 retary may work with the sponsor to maximize the oppor-
19 tunity for the sponsor to successfully demonstrate that the
20 antimicrobial drug possesses the favored characteristics of
21 high-monetary valued products identified under section
22 39900(c)(2).

23 “(c) APPROPRIATE USE OF CRITICAL NEED ANTI-
24 MICROBIAL.—

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

8 “(A) shall include—

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

10 and

11 “(ii) the appropriate use of diagnostic
12 tools, where available, such as diagnostic
13 testing for biomarkers related to anti-
14 microbial-resistant pathogens and dem-
15 onstrating improved infection diagnosis
16 and benefit with the drug, or other tar-
17 geted diagnostic approaches, to inform use
18 of the drug; 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 “(3) PUBLICATION OF CLINICAL GUIDELINES.—
9 Not later than 1 year after the Secretary makes the
10 first designation under subsection (a), and not less
11 than every 3 years thereafter, the Secretary shall
12 publish clinical guidelines in consultation with rel-
13 evant professional societies with respect to each anti-
14 microbial drug that has been approved or licensed as
15 described in subsection (a)(1) and that has been des-
16 ignated under subsection (a), which guidelines shall
17 set forth the evidence-based recommendations for
18 prescribing the drug, in accordance with the evi-
19 dence in submissions of the sponsor under para-
20 graph (1) and after consultation under paragraph
21 (2), as appropriate.

22 **“SEC. 3990-2. SUBSCRIPTION CONTRACTS.**

23 “(a) 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 with the Secretary, under a procedure
8 established by the Secretary.

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

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 meets the favored
16 characteristics identified under section
17 39900(c)(2), and deny any application for a
18 drug that meets none of such characteristics;
19 and

20 “(C) assign a monetary value to the con-
21 tract based on the regulations developed under
22 section 39900(d).

23 “(b) CRITERIA.—To qualify for a subscription con-
24 tract under this section, the sponsor of an antimicrobial

1 drug designated as a critical need antimicrobial shall agree
2 to—

3 “(1) ensure commercial and Federal availability
4 of the antimicrobial drug within 30 days of receiving
5 first payment under the contract, and sufficient sup-
6 ply for susceptibility device manufacturers;

7 “(2) identify, track, and publicly report drug
8 resistance data, patient outcomes, and trends using
9 available data related 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, Committee, Food and Drug Adminis-
18 tration, and Centers for Disease Control and Pre-
19 vention every 2 years regarding use of the anti-
20 microbial drug, including how the drug is being mar-
21 keted;

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 Secretary to ensure patient ac-
9 cess to the drug;

10 “(9) price the drug at a price that is not lower
11 than a comparable generic drug;

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

19 “(11) abide by other terms as the Secretary
20 may require.

21 “(c) AMOUNT AND TERMS OF CONTRACTS.—

22 “(1) AMOUNTS.—A subscription contract under
23 this section shall be for the sale to the Secretary of
24 any quantity of the antimicrobial drug needed over
25 the term of the contract under paragraph (2), at an

1 agreed upon price, for a total projected amount de-
2 termined by the Secretary that is not less than
3 \$750,000,000 and not more than \$3,000,000,000,
4 adjusted for inflation, accounting for the favored
5 characteristic or combination of favored characteris-
6 tics of the drug, including improved patient out-
7 comes, as determined by the Secretary, in consulta-
8 tion with the Committee, under subsection (a)(2),
9 and shall be allocated from the amount made avail-
10 able under section 39900–4(a). Not later than 6
11 months after the subscription contract is granted
12 under subsection (a), the Secretary shall provide
13 payments for purchased drugs in installments estab-
14 lished by the Secretary in consultation with the
15 sponsor of the antimicrobial drug and in accordance
16 with subsection (d)(3). Funds received by the spon-
17 sor shall be used to support criteria qualification
18 under subsection (b), the completion of post-
19 marketing clinical studies, manufacturing, other pre-
20 clinical and clinical activities, or other activities
21 agreed to by the Secretary and sponsor in the con-
22 tract.

23 “(2) TERMS.—

24 “(A) INITIAL TERM.—The initial term of a
25 contract under this subsection shall be no less

1 than 5 years or greater than the greater of 10
2 years or the remaining period of time during
3 which the sponsor has patent protections or a
4 remaining exclusivity period with respect to the
5 antimicrobial drug in the United States, as list-
6 ed in the publication of the Food and Drug Ad-
7 ministration entitled ‘Approved Drug Products
8 with Therapeutic Equivalence Evaluations’.
9 Payments may be in equal annual installments
10 with the option to redeem 50 percent of the last
11 year’s reimbursement in year 1 of the contract
12 in order to offset costs of establishing manufac-
13 turing capacity, or another subscription ar-
14 rangement to which the Secretary and sponsor
15 agree. Subscription contracts shall remain in ef-
16 fect for such period even if the infection treated
17 by such antimicrobial drug is later removed
18 from the list of infections under section
19 39900(c)(1).

20 “(B) EXTENSION OF CONTRACTS.—The
21 Secretary may extend a subscription contract
22 with a sponsor under this subsection beyond the
23 initial contract period. A single contract exten-
24 sion may be in effect not later than the date on
25 which all periods of exclusivity granted by the

1 Food and Drug Administration expire and shall
2 be in an amount not to exceed \$25,000,000 per
3 year. All other terms of an extended contract
4 shall be the same as the terms of the initial
5 contract. The total amount of funding used on
6 such contract extensions shall be no more than
7 \$1,000,000,000, and shall be allocated from the
8 amount made available under section 39900–4.

9 “(C) MODIFICATION OF CONTRACTS.—The
10 Secretary or sponsor, 1 year after the start of
11 the contract period under this subsection and
12 every 2 years thereafter, may request a modi-
13 fication of the amount of the contract based on
14 information that adjusts favored characteristics
15 in section 39900(c)(2).

16 “(3) ADJUSTMENT.—In the case of an anti-
17 microbial drug that received a transitional subscrip-
18 tion contract under section 39900(f), the amount of
19 a subscription contract for such drug under this sec-
20 tion shall be reduced by the amount of the transi-
21 tional subscription contract under such section
22 39900(f) for such drug.

23 “(4) CONTRACTS FOR GENERIC AND BIO-
24 SIMILAR VERSIONS.—Notwithstanding any other
25 provision in this part, the Secretary may award a

1 subscription contract under this section to a manu-
2 facturer of a generic or biosimilar version of an anti-
3 microbial drug for which a subscription contract has
4 been awarded under this section. Such contracts
5 shall be awarded in accordance with a procedure, in-
6 cluding for determining the terms and amounts of
7 such contracts, established by the Secretary.

8 “(d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REV-
9 ENUE LIMITATIONS.—

10 “(1) IN GENERAL.—Pursuant to a contract en-
11 tered into under this section, during the term of
12 such a contract, the annual net revenue from sales
13 of the applicable antimicrobial drug for beneficiaries
14 or enrollees in Federal health care programs shall be
15 subtracted from the annual payment installments
16 determined in the subscription contract. The Sec-
17 retary shall coordinate with the relevant agencies of
18 the Federal Government to carry out this subsection
19 in a manner that ensures minimal disruption to how
20 a health care provider currently acquires applicable
21 antimicrobial drugs.

22 “(2) REGULATIONS.—To carry out this sub-
23 section, the Secretary shall promulgate regulations
24 to identify the Federal health care programs applica-
25 ble under this section and to establish the method-

1 ology and data collection requirements necessary to
2 determine the amount to be subtracted from any
3 contract. Any methodology established for the collec-
4 tion of data and calculation of the amount to be sub-
5 tracted from any contract shall take into account
6 any legally mandated or voluntary discounts and re-
7 bates provided by the manufacturer of the applicable
8 antimicrobial drug to the government programs that
9 pay for such drugs subject to a contract agreement
10 entered into pursuant to subsection (c)(2).

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

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

17 “(B) FEDERAL HEALTH CARE PROGRAM.—
18 The term ‘Federal health care program’ has the
19 meaning given such term in section 1128B(f) of
20 the Social Security Act, except that, for pur-
21 poses of this subsection, such term includes the
22 health insurance program under chapter 89 of
23 title 5, United States Code.

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

4 “(1) the sponsor—

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

8 “(B) fails to meet criteria under subsection
9 (b); or

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

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

21 “(3) if the total revenue of the sponsor from
22 government programs that pay for drugs subject to
23 a contract agreement entered into pursuant to sub-
24 section (c)(2), for a year exceeds the amount of the

1 subscription contract paid by the Secretary for that
2 year.

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

9 **“SEC. 3990-3. ENCOURAGING APPROPRIATE USE OF ANTI-
10 BIOTICS, COMBATING RESISTANCE, AND IM-
11 PROVING PATIENT OUTCOMES.**

12 “(a) ESTABLISHMENT OF HEALTH FACILITY GRANT
13 PROGRAM.—

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

1 “(A) to judiciously use antimicrobial drugs,
2 such as by establishing or implementing appro-
3 priate use programs, including infectious dis-
4 ease telehealth programs, using appropriate di-
5 agnostic tools, partnering with academic hos-
6 pitals, increasing health care-associated infec-
7 tion reporting, and monitoring antimicrobial re-
8 sistance and patient outcomes; and

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

17 “(2) PRIORITIZATION.—In awarding grants
18 under paragraph (1), the Secretary shall prioritize
19 hospitals or skilled nursing facilities without an ex-
20 isting program to judiciously use antimicrobial
21 drugs, subsection (d) hospitals (as defined in sub-
22 paragraph (B) of section 1886(d)(2) of the Social
23 Security Act that are located in rural areas (as de-
24 fined in subparagraph (D) of such section), critical
25 access hospitals (as defined in section 1861(mm)(1)

1 of such Act), hospitals serving Tribal-populations,
2 and safety-net hospitals.

3 “(3) FUNDING.—Of the amounts appropriated
4 under section 39900–4, the Secretary shall reserve
5 \$500,000,000 to carry out this subsection.

6 “(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC
7 USE, RESISTANCE, AND PATIENT OUTCOMES.—

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—

13 “(A) appropriate conditions, patient out-
14 comes, and measures causally related to anti-
15 bacterial resistance, including types of infec-
16 tions, the causes for infections, the types of pa-
17 tients with infections, and whether infections
18 are acquired in a community or hospital setting,
19 increased lengths of hospital stay, increased
20 costs, and rates of mortality; and

21 “(B) changes in bacterial resistance to
22 antimicrobial drugs in relation to patient out-
23 comes, including changes in percent resistance,
24 prevalence of antibiotic-resistant infections,
25 rates of patient survival, patient symptoms and

1 function in their daily lives, and other such
2 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 AND PA-
19 TIENT OUTCOMES DATA.—The Secretary, acting
20 through the Director of the Centers for Disease
21 Control and Prevention, shall intensify and expand
22 efforts to collect antibiotic resistance and patient
23 outcomes data and encourage adoption of the Anti-
24 biotic Use and Resistance Module within the Na-
25 tional Healthcare Safety Network among all health

1 care facilities across the continuum of care, includ-
2 ing, as appropriate, acute care hospitals, dialysis fa-
3 cilities, nursing homes, ambulatory surgical centers,
4 and other ambulatory health care settings in which
5 antimicrobial drugs are routinely prescribed. The
6 Secretary shall seek to collect such data from elec-
7 tronic medication administration reports and labora-
8 tory systems to produce the reports described in
9 paragraph (4).

10 “(4) PUBLIC AVAILABILITY OF DATA.—The
11 Secretary, acting through the Director of the Cen-
12 ters for Disease Control and Prevention, shall, for
13 the purposes of improving the monitoring of impor-
14 tant trends in patient outcomes in relation to anti-
15 bacterial resistance—

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

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

22 **“SEC. 3990-4. APPROPRIATIONS.**

23 “(a) IN GENERAL.—To carry out this part, there are
24 hereby appropriated to the Secretary, out of amounts in

1 the Treasury not otherwise appropriated, \$6,000,000,000,
2 for fiscal year 2023, to remain available 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.

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. 3990-5. STUDIES AND REPORTS.**

14 “(a) IN GENERAL.—Not later than 6 years after the
15 date of enactment of this part, the Comptroller General
16 of the United States shall complete a study on the effec-
17 tiveness of this part in developing priority antimicrobial
18 drugs and improving patient outcomes. Such study shall
19 examine the indications for, usage of, development of re-
20 sistance with respect to, and private and societal value of
21 critical need antimicrobial drugs, and the impact of the
22 programs under this part on patient outcomes and mar-
23 kets of critical need antimicrobial drugs. The Comptroller
24 General shall report to the Committee on Health, Edu-
25 cation, Labor, and Pensions of the Senate and the Com-

1 mittee on Energy and Commerce of the House of Rep-
2 resentatives 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) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—
11 Not later than 3 years after the date of enactment of this
12 part, the Director of the Centers for Disease Control and
13 Prevention shall publish a report on antimicrobial prophyl-
14 lactics.

15 **“SEC. 3990–6. DEFINITIONS.**

16 “In this part—

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

18 “(A) means, subject to subparagraph (B),
19 a product that is—

20 “(i) a drug that directly inhibits rep-
21 lication of or kills bacteria or fungi rel-
22 evant to the proposed indication at con-
23 centrations likely to be attainable in hu-
24 mans to achieve the intended therapeutic
25 effect; or

1 “(ii) a biological product that acts di-
2 rectly on bacteria or fungi or on the sub-
3 stances produced by such bacteria or fungi;
4 and

5 “(B) does not include—

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

11 “(ii) a vaccine; and

12 “(2) the term ‘Committee’ means the Com-
13 mittee on Critical Need Antimicrobials established
14 under section 3990O.”.