116TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as ''The Pioneering Antimicrobial Subscriptions To End Up Surging Resistance Act of 2020'' or ''The PASTEUR Act''.

SEC. 2. ESTABLISHMENT OF COMMITTEE AND SUBSCRIPTION MODEL.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary shall establish

a Committee on Critical Need Antimicrobials and appoint members to the Committee.

(b) MEMBERS.—

(1) IN GENERAL.—The Committee shall consist of—

(A) at least one representative from each of the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services;

(B) 5 individuals who are infectious disease specialists or other health experts with expertise in antimicrobial resistance; and

(C) at least one patient advocate.

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

(3) CONFLICTS OF INTEREST.—In appointing members under subparagraph (B) and (C) of paragraph (1), the Secretary shall ensure that no member receives compensation in any manner from an entity that develops antimicrobials or that might benefit from antimicrobial development.

(c) DUTIES.—Not later than 1 year after the appointment of the initial members of the Committee, the Committee shall do the following:

(1) Develop a list of microbes for which new drug development is needed, taking into account infections for which there is an unmet medical need, findings from the most recent Antibiotic Resistance Threats in the United States Report issued by the Centers for Disease Control and Prevention, an anticipated unmet medical need, or resistance with respect to multiple other drugs.

(2) Develop guidance outlining favored characteristics of critical need antimicrobials that are evidence-based and designed to prevent or treat the infections and assign monetary values to each such characteristic. Such favored characteristics of a drug shall include—

(A) drugs treating infections caused by microbes on the list under paragraph (1);

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

(C) being a first-approved drug that treats certain multi-drug resistant infection, and, to a

lesser extent, second and third drugs that treat such infection;

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

(E) any other characteristics the Committee determines necessary.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the appointment of the initial members of the Committee, the Secretary shall issue proposed regulations setting forth a process by which the sponsors can apply for a drug to become a critical need antimicrobial under section 3, how subscription contracts under such section shall be established and paid, and other elements of the subscription contract process, in accordance with this Act.

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

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

(e) LIST OF MICROBES.—The Committee shall update the list of microbes under subsection (c)(1) every 2 years.

(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

(1) IN GENERAL.—During the period beginning on the date of enactment of this Act and ending on the date that the Committee finalizes the subscription contract guidance under subsection (d), the Committee may use up to $750,000,000 of the amount appropriated under section 5(a) to engage in transitional subscription contracts of up to 3 years in length with antimicrobial developers, as determined by the Committee, that are developing drugs treating infections listed in the most recent report entitled ''Antibiotic Resistance Threats in the United States'' issued by the Centers for Disease Control and Prevention, and may include qualified infectious disease products (as defined in section 505E(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f(g)). Funds made available under such contracts may be used for a variety of purposes including to support the completion of

postmarketing clinical studies, manufacturing, and other preclinical and clinical efforts.

(2) REQUIREMENTS.—The Committee may enter into a contract under paragraph (1)—

(A) if the Committee determines that the drug demonstrates a significant clinical advancement in treating an infection for which there is an unmet clinical need, an anticipated clinical need, or multidrug resistance; and

(B) subject to terms including—

(i) that the Secretary shall cease any payment installments under a transitional subscription contract if the sponsor does not—

(I) ensure commercial and Federal availability of the drug within 30 days of receiving first payment under the contract;

(II) identify, track, and publicly report drug resistance data and trends using available data related to the drug;

(III) develop and implement education and communications strategies for health care professionals and pa-

tients about appropriate use of the drug;

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

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

(VI) make meaningful progress toward completion of Federal Drug Administration-required post-marketing studies; and

(ii) other terms as determined by the Secretary.

(3) TRANSITIONAL GUIDANCE.—Not later than 30 days after the appointment of the initial members of the Committee, the Committee shall issue transitional guidance outlining the drugs that are eligible for transitional subscription contracts under paragraph (1), the requirements to enter into a transitional subscription contract under paragraph (2), and the process by which drug developers can

enter into transitional subscription contracts with the Secretary under this subsection.

(4) PAYMENT MECHANISM.—No later than 30 days after the enactment of this Act, the Secretary shall determine the agency or office in the Department of Health and Human Services that will manage the subscription contracts during the period described in paragraph (1).

SEC. 3. CRITICAL NEED ANTIMICROBIAL DRUG APPLICATION AND PAYMENT THROUGH SUBSCRIPTION CONTRACTS.

(a) IN GENERAL.—

(1) SUBMISSION OF REQUEST.—The sponsor of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for an antimicrobial drug may request that the Secretary designate the drug as a critical need antimicrobial. A request for such designation may be submitted during clinical development of such drug or after filing of such an application, and shall be submitted not later than 5 years after the date of approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licen-

sure under section 351(a) of the Public Health Service Act.

(2) CONTENT OF REQUEST.—A request under paragraph (1) shall include information, such as clinical and preclinical data, a list of the favorable characteristics described in section 2(c)(2), and any other material that the Committee requires.

(3) REVIEW BY COMMITTEE.—The Committee shall review all requests for designation submitted under this subsection, assess all required application components, and determine if the drug is likely to meet the favorable characteristics identified in the application upon the completion of clinical development. After review, the Committee shall approve or deny each request for designation. If the Committee approves a request, it shall publish the value of the contract that the critical need antimicrobial developer would be eligible to receive if such developer successfully demonstrates that the drug meets the maximum value of the favored characteristics listed in the application.

(4) LENGTH OF DESIGNATION PERIOD.—A designation granted under this section shall be in effect for a period of 10 years after the date that the designation is approved, and shall remain in effect for

such period even if the microbe treated by such drug is later removed from the microbe list under section 2(c)(1).

(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a critical need antimicrobial designation is granted during clinical development of a drug, the Secretary shall work with the sponsor to maximize the opportunity for the sponsor to successfully demonstrate that the drug possesses the favored characteristics of high-quality products identified under section 2(c)(2).

(c) APPROPRIATE USE OF CRITICAL NEED ANTIMICROBIAL.—

(1) IN GENERAL.—The sponsor of a drug that receives designation under subsection (a) shall submit an appropriate use plan to the Committee within 30 days of application approval for appropriate use of diagnostics for consideration by providers in prescribing the drug. A diagnostic plan—

(A) shall include—

(i) the appropriate use of the drug; and

(ii) the appropriate use of diagnostic tools such as procalcitonin, PCR-based methods, or other targeted diagnostic approaches, to inform use of the drug; and

(B) may be developed in partnership with the Secretary or another entity.

(2) CONSULTATION.—The Secretary shall work with an advisory panel of patient advocates and infectious disease specialists to ensure that clinical guidelines issued by the Secretary under paragraph (3) with respect to a drug designated under subsection (a) includes the use of appropriate diagnostic approaches, taking into consideration the diagnostic plan submitted by a sponsor under paragraph (1).

(3) PUBLICATION OF CLINICAL GUIDELINES.—The Secretary shall publish clinical guidelines with respect to each drug designated under subsection (a) which shall set forth the requirements practitioners shall follow in prescribing the drug, in accordance with the submissions of the sponsor under paragraph (1) and after consultation under paragraph (2), as appropriate.

SEC. 4. SUBSCRIPTION CONTRACTS.

(a) APPLICATION FOR A SUBSCRIPTION CONTRACT.—

(1) SUBMISSION OF APPLICATIONS.—Upon approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or licensure under section 351(a) of the Public Health Serv-

ice Act (42 U.S.C. 262(a)), the sponsor of a drug designated as a critical need antimicrobial under section 3 may submit an application for a subscription contract with the Secretary, under a procedure established by the Secretary.

(2) REVIEW OF APPLICATIONS.—The Committee shall—

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

(B) determine the extent to which the critical need antimicrobial meets the favored characteristics identified under section 2(c)(2), and deny any application for a drug that meets none of such characteristics; and

(C) assign a monetary value to the contract based on the regulation developed under 2(d).

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

(1) ensure commercial and Federal availability of the drug within 30 days of receiving first payment under the contract, and sufficient supply for susceptibility device manufacturers;

(2) identify, track, and publicly report drug resistance data and trends using available data related to the drug;

(3) develop and implement education and communications strategies for health care professionals and patients about appropriate use of the drug;

(4) submit an appropriate use assessment to the Food and Drug Administration every 2 years regarding use of the drug, including how the drug is being marketed;

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

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

(7) complete any postmarketing studies required by the Food and Drug Administration in a timely manner;

(8) produce the drug at a volume negotiated with the Secretary;

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

(10) abide by other terms as the Committee may require.

(c) TERM AND AMOUNT OF CONTRACTS.—

(1) AMOUNTS.—A contract under this section shall be for the sale to the Secretary of a quantity of the drug, at an agreed upon price, for a total projected amount determined by the Secretary that is not less than $750,000,000 and not more than $3,000,000,000, accounting for the favored characteristics of the drug, as determined by the Committee under subsection (a)(2), and shall be allocated from the amount made available under section 5(a). Not later than 6 months after the application is submitted under subsection (a), the Secretary shall provide payments for purchased drugs in installments established by the Secretary in consultation with the sponsor of the drug. Funds received by the sponsor may be used to support criteria qualification under subsection (b), the completion of postmarketing clinical studies, manufacturing, and other preclinical and clinical activities agreed to by the Secretary and sponsor in the contract with respect to the drug.

(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 drug. 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 microbe treated by such drug is later removed from the microbe list under section 2(c)(1).

(B) EXTENSION OF CONTRACTS.—The Secretary may extend subscription contracts beyond the initial contract period with a generic brand manufacturer of the drug receiving a subscription contract or the original drug manufacturer. A single contract extension may be in effect not later than the date on which all periods of exclusivity granted by the Food and Drug Administration expire and shall be in an amount not to exceed $25,000,000 per year. All other terms of an extended contract shall be the same as the terms of the initial contract. The

total amount of funding used on such contract extensions shall be no more than $1,000,000,000, and shall be allocated from the amount made available under section 5.

(d) ANNUAL REVENUE LIMITATIONS.—Pursuant to a contract awarded under this section, during the term of such a contract, the annual revenue from sales of the drug for beneficiaries or enrollees in the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), the TRICARE program, the health program of the Department of Veterans Affairs, and health care delivered through the Bureau of Prisons, the Department of Homeland Security, and the Indian Health Service programs shall be subtracted from the payment installment determined in the subscription contract. The Secretary shall coordinate with the Centers for Medicare & Medicaid Services and other relevant branches of the Federal Government to carry out this subsection in a manner that ensures minimal disruption to how a health care provider currently acquires antimicrobial drugs.

(e) PRIVATE PAYER AND INTERNATIONAL PAYER PARTICIPATION.—The Secretary shall make efforts to increase the participation of domestic private payors and

international payors in subscription contracts that are similar to the subscription contracts authorized under this Act.

[(f) ENCOURAGING HOSPITAL PARTICIPATION.—]

(1) ESTABLISHMENT OF GRANT PROGRAM.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall coordinate with the Administrator of the Health Resources and Services Administration, the Administrator of the Centers for Medicare & Medicaid Services, and other relevant agencies, to establish a grant program to support hospital efforts—

(i) to judiciously use antimicrobial drugs; and

(ii) to participate in the National Healthcare Safety Network Antimicrobial Use and Resistance Module of the Centers for Disease Control and Prevention or a similar reporting program, as specified by the Secretary, relating to antimicrobial drugs.

(B) PRIORITIZATION.—In awarding grants under subparagraph (A), the Secretary shall prioritize 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 defined in subparagraph (D) of such section), critical access hospitals (as defined in section 1861(mm)(1) of such Act (42 U.S.C. 1395x(mm)(1)), and safety-net hospitals.

[(2) MEDICARE REIMBURSEMENT.—Section 1886 of the Social Security Act (42 U.S.C. 1395ww)) is amended by adding at the end the following new subsection:]

[“(u) ENCOURAGING APPROPRIATE USE OF ANTIMICROBIAL DRUGS.—]

[“(1) IN GENERAL.—[*Note: alternative approach would be to make this a condition of participation. Review whether/how this would apply to critical access hospitals under section 1814(l).*] In order to provide an incentive for applicable hospitals to judiciously use antimicrobial drugs, with respect to an applicable discharge from a subsection (d) hospital during fiscal year [2030] or a subsequent fiscal year, the amount of payment under this section or section 1814(b)(3), as applicable, for such discharges during the fiscal year shall be equal to [____] percent of the amount of payment that

would otherwise apply to such discharges under this section or section 1814(b)(3) (determined after the application of subsections (o), (p), and (q) and section 1814(l)(4) but without regard to this subsection).]

[''(2) DEFINITIONS.—]

[''(A) APPLICABLE DISCHARGE.—In this subsection, the term 'applicable discharge' means a discharge in which an antimicrobial drug was furnished.]

[''(B) APPLICABLE HOSPITAL.—The term 'applicable hospital' means a subsection (d) hospital that is not participating in the National Healthcare Safety Network Antimicrobial Use and Resistance Module of the Centers for Disease Control and Prevention or a similar reporting program, as specified by the Secretary, relating to antimicrobial drugs, as determined on the date of the applicable discharge involved.''.]

(g) FAILURE TO ADHERE TO TERMS.—The Secretary shall cease any payment installments under a contract under this section if—

(1) the sponsor—

(A) permanently withdraws the drug from the market in the United States;

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

(C) does not complete any postmarket studies required by the Food and Drug Administration; or

(2) the annual international and private insurance market revenues with respect to a drug (not counting any subscription revenues from any source pursuant to a contract under this subsection) exceed 5 times the average annual amount of the subscription contract paid by the Secretary.

SEC. 5. APPROPRIATIONS.

(a) IN GENERAL.—To carry out this Act, there are hereby appropriated to the Secretary, out of amounts in the Treasury not otherwise appropriated, $11,000,000,000, for fiscal years [xxx], to remain available until expended.

(b) EMERGENCY DESIGNATION.—

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

(2) DESIGNATION IN SENATE.—In the Senate, this subsection is designated as an emergency requirement pursuant to section 4112(a) of H. Con.

Res. 71 (115th Congress), the concurrent resolution on the budget for fiscal year 2018.

SEC. 6. STUDY AND REPORT.

Not later than 6 years after the date of enactment of this Act, the Secretary shall complete a study on the effectiveness of this Act in developing priority antimicrobial drugs. Such study shall examine the indications for, usage of, development of resistance with respect to, and private and societal value of critical need antimicrobials, and the impact of the programs under this Act on patients and markets of critical need antimicrobials. The Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the findings of such study, and shall make such report publicly available on the internet website of the Department of Health and Human Services.

SEC. 7. DEFINITIONS.

In this Act—

(1) the term ''drug'' has the meaning given such term under section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g));

(2) the term ''Committee'' means the Committee on Critical Need Antimicrobials established under section 2; and

(3) the term ''Secretary'' means the Secretary of Health and Human Services.