

The Pioneering Antimicrobial Subscriptions To End Up surging Resistance (PASTEUR) Act of 2021

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Section-by-Section

Section 1: SHORT TITLE

The title of the bill is “The Pioneering Antimicrobial Subscriptions To End Up surging Resistance Act of 2021” or “The PASTEUR Act.”

Section 2: DEVELOPING ANTIMICROBIAL INNOVATIONS

Amends the Public Health Service Act to add “Part W-Developing Antimicrobial Innovations”.

Section 39900: ESTABLISHMENT OF COMMITTEE, SUBSCRIPTION MODEL, ADVISORY GROUP

Subsection (a): In General –

Within 60 days of passage, the Secretary of the Department of Health and Human Services (HHS) will establish and appoint members to a new “Committee on Critical Need Antimicrobials” (referred to in this document as the “Committee”).

Subsection (b): Members –

It will consist of a Chair, appointed by the HHS Secretary, and at least one representative from the National Institute of Allergy and Infectious Diseases (NIAID), The Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research and Development Authority (BARDA), the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), the Veterans Health Administration (VHA), and the Department of Defense (DoD).

Subsection (c) Duties –

Within 1 year of appointment, the Secretary, in collaboration with the Committee and the Critical Needs Antimicrobials Advisory Group (see subsection (g)) shall (1) develop a list of infections for which new antimicrobial drugs are needed, and (2) develop regulations outlining evidence-based favored characteristics of high-quality drugs designed to prevent or treat infections. The Committee shall also assign monetary values to these characteristics.

Favored characteristics shall include but will not be limited to:

- Treats infections that are included on the list that the Committee has developed;
- Improves clinical outcomes over alternative therapies for patients with multidrug resistant infections;

- First approved antimicrobial drug that has the potential to treat the unmet medical needs of a serious infection. Second and third drugs might receive a smaller boost in value;
- The method of administration, with preference given to oral administration;
- Has a novel active moiety, target, or mode of action not previously approved;
- Addressing a multi-drug resistant infection through a novel mechanism; and
- Receiving a transitional subscription contract (see subsection (f)).

Subsection (d) Regulations -

Within 1 year of Committee appointments, the Secretary shall develop regulations outlining the process by which the sponsors can apply to become a ‘critical need antimicrobial,’ and how these contracts will be established and paid, how favored characteristics will be weighed, and any other elements of the subscription plan process.

The public comment and meetings period will last 120 days. After the close of this period, the Secretary will have 120 days to finalize and publish the guidance. Additionally, within 6 months, the Secretary will propose and establish the Subscription Contract Office (SCO) to manage the subscription contracts.

Subsection (e) List of Infections –

The Secretary and Committee shall update the list of infections every 2 years, at least.

Subsection (f) Transition Subscription Contracts -

While the Secretary finalizes the subscription contract regulations, the Secretary may use up to \$1,000,000,000 to enter into contracts of up to 3 years with antimicrobial developers that are developing drugs to treat infections listed in the CDC issued report entitled “Antibiotic Resistance Threats in the United States.” Transitional contracts may be awarded to developers of drugs that are Qualified Infectious Disease Products or other innovative products.

The Secretary may enter into a transitional contract for a drug that is (1) intended to treat an infection for which there is an unmet clinical need, an anticipated clinical need, or multidrug resistance, and (2) in a phase 3 clinical study or approved by the FDA.

In order to receive contract payments, sponsors must follow the following terms and conditions:

- Ensure commercial and federal availability of their drug within 30 days of receiving first payment;
- Identify, track, and publicly report available drug resistance data and trends related to their critical need antimicrobial;
- Develop education and communications strategies for health care professionals and patients about appropriate use of their drug;
- Submit a plan for registering their drug in other countries where an unmet need exists;

- 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;
- Make meaningful progress toward completion of FDA-required post-marketing studies; and
- Anything else the Secretary determines.

Within 120 days of the Committee appointments, the Secretary will issue transitional guidance detailing drug eligibility, the requirements to enter into a transitional subscription plan contract, and the process by which drug developers can enter into transitional subscription plan contracts.

Within 30 days of enactment, the Secretary will determine the agency or office within HHS that will manage the transitional subscription plan contracts, which may be different than the SCO.

Subsection (g): Critical Need Antimicrobial Advisory Group –

Within 30 days, the Secretary, in collaboration with the Committee, will establish a “Critical Need Antimicrobial Advisory Group” (referred to as the “Advisory Group”). The Advisory Group will include at least 6 members who are infectious disease specialists or other health experts, and at least 5 patient advocates.

Section 399PP: CRITICAL NEED ANTIMICROBIAL DRUG APPLICATION AND PAYMENT THROUGH SUBSCRIPTION CONTRACTS

Subsection (a) In General –

An antimicrobial drug sponsor may request designation as a ‘critical need antimicrobial’ during clinical development or after filing for licensure. Applications must be submitted within 5 years of licensure. The applications will include information such as clinical and preclinical data and the list of favorable characteristics that the developer believes the drug satisfies.

The Secretary may approve the request if – upon completion of clinical development - the drug is likely to meet the favorable characteristics identified in the application. If approved, the value of the contract the drug developer would be eligible to receive will be published. Once a drug receives this designation, the designation cannot be revoked for 10 years, even if the microbe it treats is later removed from the microbe list.

Subsection (b) Development of Designated Drugs –

If a critical need antimicrobial designation is granted during clinical development of an antimicrobial drug, the Secretary may work with the sponsor to successfully demonstrate that the drug possesses the favored characteristics.

Subsection (c) Appropriate Use of Critical Need Antimicrobial -

Within 90 days of application approval, sponsors shall submit a plan to the Secretary for appropriate use of diagnostics to be used in developing clinical guidelines. Plans will include the appropriate

use of the drug and diagnostic tools. The Secretary will consult with relevant stakeholders and the Advisory Group to ensure that clinical guidelines include the use of appropriate diagnostic approaches, taking into consideration the diagnostic plan submitted by the sponsor. The Secretary will subsequently publish these clinical guidelines.

Section 399QQ: SUBSCRIPTION CONTRACTS

Subsection (a) Application for a Subscription Contract –

After approval or licensure, the sponsor of a drug designated as a ‘critical need antimicrobial’ may apply for a subscription contract. The SCO, in consultation with the Committee, will review all applications, assess required application components, determine the extent to which the drug meets the favored characteristics, and assign a monetary value to the contract based on the number and value of those characteristics. If the drug does not meet any of the favored characteristics, the SCO will deny the application.

Subsection (b) Criteria -

To qualify for a subscription contract, sponsors must agree to the following terms and conditions:

- Ensure commercial and federal availability of their drug within 30 days of receiving first payment, as well as sufficient supply for susceptibility device manufacturers;
- Identify, track, and publicly report drug resistance data and trends related to their critical need antimicrobial using available data related to the drug;
- Develop education and communications strategies for health care professionals and patients about appropriate use of their drug;
- Submit an appropriate use assessment to the Secretary, the Committee, FDA, and CDC every two years regarding use of their drug;
- Submit a plan for registering their drug in additional countries where an unmet need exists;
- Ensure a reliable drug supply chain, where any interruption to the supply chain will not last for more than 60 days;
- Complete any post-marketing studies required by the FDA in a timely manner;
- Produce their drug at a volume negotiated with the Secretary;
- Price their drug no lower than a comparable generic drug;
- Abide by manufacturing and environmental best practices;
- And anything else the Secretary deems necessary

Subsection (c) Terms and Amount of Contracts -

Contracts shall range from \$750 million to \$3 billion, and will be based on the value of favored characteristics that the drug possesses. The Secretary shall have final determination of contract size and shall, no later than 6 months following application, begin to provide payments in installments.

Contracts under this subsection must run for a period of at least 5 years. The section authorizes 3 possible maximum periods; these are: the greater of (a) 10 years, (b) the remaining time on the

sponsor's patent protections, or (c) the remaining exclusivity period with respect to the antimicrobial drug.

Payments will be made in equal annual installments with an option for companies to redeem part of the last year contract value in the first year of the contract in order to offset costs of establishing manufacturing capacity. The subscription contracts will remain in place even if a microbe that is treated by the drug is later removed from the Committee's list of infections.

The Secretary can choose to negotiate secondary contracts for subscription plans to extend beyond the initial period; \$1 billion of the initial funding will be used for this purpose. These contracts will not exceed \$25 million per year. Provisions in these contracts will mirror those in the initial contract.

Subsection (d) Annual Antimicrobial Drug Sponsor Revenue Limitations -

During years when the contract is in place, annual sponsor revenue from critical need antimicrobial use by recipients of Medicare, Medicaid, TRICARE, VHA, health care delivered through the Bureau of Prisons, Department of Homeland Security, and Indian Health Services programs will be tabulated and subtracted from the annual subscription payment. The Secretary shall coordinate with CMS and other relevant branches of the federal government to operationalize this provision.

Subsection (e) Failure to Adhere to Terms –

The Secretary shall cease any payment installments if the sponsor:

- Permanently withdraws drug from the U.S. market;
- Fails to meet the terms of the subscription plan contracts as previously outlined;
- Does not complete any post-marketing studies as required by the FDA;
- If annual international and private insurance market revenues (not counting revenues from subscription contracts paid by this Act) exceed 5 times the average annual amount of the subscription contract paid by the Secretary; or
- If the revenue under the specified government programs exceeds the annual contract payment.

Subsection (f) Private Payer and International Payer Participation –

The Secretary shall explore practices to increase the participation of domestic private payers and international payers in such subscription plans.

Section 399RR: ENCOURAGING APPROPRIATE USE OF ANTIBIOTICS AND COMBATING RESISTANCE

Subsection (a) Establishing of Hospital Grant Program –

The Secretary and CDC Director will coordinate with the Administrators of the Human Resources and Services Administration and CMS, the National Coordinator for Health Information

Technology, and other relevant agencies to establish a grant program to support hospital efforts to (a) judiciously use antimicrobial drugs and, (b) participate in the CDC’s National Healthcare Safety Network (NHSN) Antimicrobial Use and Resistance (AUR) Module, the Emerging Infections Program, or a similar reporting module.

The Secretary will prioritize rural hospitals, critical access hospitals, and safety-net hospitals when awarding grants; \$500 million shall be utilized to carry out this subsection.

Subsection (b) Surveillance and Reporting of Antibiotic Use and Resistance –

The Secretary will intensify and expand efforts to collect antibiotic resistance data by:

- Utilizing the information gathered by the NHSN and other surveillance systems to assess both the causes of antibacterial resistance, and the changes in bacterial resistance to antimicrobial drugs.
- Work with federal agencies, health care organizations, and other entities to obtain reliable and comparable human antibiotic drug consumption data by State or metropolitan areas.

The Secretary will encourage the adoption of the AUR Module within the NHSF among all health care facilities, particularly in settings where antimicrobial drugs are routinely prescribed. In order to improve the monitoring of patient outcome trends related to antibacterial resistance, the Secretary will make the data publicly available through reports issued on a regular basis (not less than annually); and examine opportunities to make such data available in near real time.

Section 399SS: APPROPRIATIONS

The legislation provides \$11 billion in initial funding via emergency supplemental direct appropriations that will be used to support the program until expended.

Section 399TT: STUDIES AND REPORTS

Subsection (a) In General -

Within 6 years, the Government Accountability Office will complete a study on the effectiveness of this program for developing critical need antimicrobial drugs. The findings will be sent to Congress, and subsequently made publicly available.

Additionally, the CDC will conduct annual reports on Antibiotic Use in the United States and within 3 years, publish a report on antimicrobial prophylactics.

Section 399UU: DEFINITIONS

Defines the term “antimicrobial drug” for the purposes of this Act.