

# The PASTEUR Act

U.S. Senators Michael F. Bennet (D-Colo.) and Todd Young (R-Ind.)

The Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act establishes a delinked subscription program to encourage innovative antimicrobial drug development targeting the most threatening infections, improve the appropriate use of antibiotics, and ensure domestic availability when needed.

## **Establishment of Subscription Model for Critical Need Antimicrobials:**

- The Secretary of the Department of Health and Human Services (HHS) will appoint a new ‘Committee on Critical Need Antimicrobials’ with representatives from relevant federal agencies.
- The HHS Secretary will appoint an ‘Critical Need Antimicrobials Advisory Group’ including patient advocates and outside experts.
- HHS and the Committee, with support from the Advisory Group, will identify infections to help target novel antimicrobial development, select an office or agency to manage the subscription program, and develop regulations and guidance determining monetary valuation and terms of subscription contracts.
- Contract value will be determined by evidence-based preferred drug characteristics to incentivize development of innovative antibiotics.
- Contracts will be fully delinked and payments will be adjusted down by any amount Federal health programs pay for the drug.

## **Transition Measures:**

- During a transition period, the HHS Secretary, through an appropriate office or agency, may use funding to enter into smaller contracts with companies developing innovative antimicrobial drugs.
- Transitional contracts will include terms of participation, including developing appropriate use strategies, the completion of FDA-required postmarketing studies, and a reliable supply chain.

## **Critical Need Antimicrobial Designation and Valuation:**

- An antimicrobial drug developer can apply to receive a ‘critical need antimicrobial’ designation. HHS will evaluate whether the drug meets preferred characteristics and determine the drug’s subscription contract eligibility and value.
- A drug developer may apply to HHS for a subscription contract at or within five years following FDA approval. Contracts will range from \$750 million to \$3 billion and will be paid out over a period of up to 10 years or through the length of patent exclusivity. In return, patients covered by federal insurance programs will receive these drugs at no cost.
- HHS and manufacturers can negotiate smaller secondary contracts to extend subscription plans or, in the case of new postmarket information, adjust the value of subscription plans.

## **Subscription Contract Terms, Conditions, and Appropriate Use:**

- Drug developers must adhere to certain requirements, including ensuring product availability, tracking resistance data, supporting appropriate use, and postmarketing studies.
- The Secretary will work with the Advisory Group and professional societies to develop timely clinical guidelines for using critical need antimicrobials.
- Providers will be encouraged to report antibiotic use through the CDC National Healthcare Safety Network Antimicrobial Use and Resistance module and other programs to improve appropriate use.
- HHS and the CDC will use health surveillance systems to collect and report on antibiotic use and resistance data.

## **Funding and Reports:**

- Congress will provide \$11 billion to support the program over 10 years.
- Within six years, the Government Accountability Office will conduct a study on the program’s effectiveness and will be sent to Congress.
- The CDC will conduct annual reports on Antibiotic Use in the United States and reports on both antifungal resistance and antimicrobial prophylactics, like vaccines.