

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

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What is Antimicrobial Resistance? Antimicrobials – including antibiotics and antivirals – are medicines used to treat and prevent infections in humans, animals and plants. Antimicrobial resistance (AMR) occurs when bacteria, viruses, fungi, and parasites mutate and no longer respond to these medicines. As a result, treating common infections becomes harder, or in some cases impossible, increasing the risk of disease spread, severe illness and death.

Why is Antimicrobial Resistance an Issue of Concern? The rapid emergence of resistant antimicrobials has been primarily by the misuse and overuse of antimicrobials in humans, animals, and plants. High rates of resistance against antibiotics frequently used to treat common infections have been observed worldwide. For example, the rate of resistance to *fluroquinolone*, an antibiotic frequently used to treat urinary tract infections, is widespread, and in many countries the treatment is now ineffective in more than half of patients.

In fact, AMR has become so widespread that in 2019 the World Health Organization published the first ever list of 12 families of bacteria that pose the greatest threat to human health. These bacteria are not only resistant to multiple antibiotics, but possess the ability to pass along their drug resistant capacities to other bacteria. In the United States, more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 people die as a result. Additionally, the estimated national cost to treat infections caused by the most common multi-drug resistant germs found in health care is estimated to be more than \$4.6 billion annually.

The AMR crisis has been further exacerbated by a lack of new drug development by the pharmaceutical industry due to reduced economic incentives and challenging regulatory requirements. In recent years, many of the innovative antibiotic companies working to develop new antimicrobials have filed for bankruptcy and stopped producing these critical drugs completely.

The PASTEUR Act: The Pioneering Antimicrobial Subscriptions To End Up surging Resistance (PASTEUR) Act seeks to address this market failure and increase public health preparedness by keeping novel antibiotics on the market and improving appropriate use across the health care system. While current reimbursement between the government and drug makers base payment on volume, the PASTEUR Act would establish a subscription-style model which would offer antibiotic developers an upfront payment in exchange for access to their antibiotics, encouraging innovation and ensuring our health care system is prepared to treat resistant infections.

The PASTEUR Act Would:

- *Form a Committee on Critical Need Antimicrobials*, consisting of representatives from relevant federal agencies, as well as doctors, patients, and outside experts, to develop and implement necessary guidance regarding infections of concern, and the favored characteristics of potential treatments.
- *Establish a Subscription Model* to encourage innovative antimicrobial drug development aimed at treating drug-resistant infections. This model will be delinked, meaning that participating developers would not receive income, as a part of their subscription payments, based on volume or quantity of sales.
- *Terms & Conditions* of the subscription contracts would include product availability to individuals on a government health insurance plan, supporting appropriate use, and completion of post market studies. These contracts could be valued between \$750 million and \$3 billion.
- *Build on Existing Frameworks* to improve appropriate use through the CDC National Healthcare Safety Network and other programs to collect and report on antibiotic use and resistance data.
- *Include Transition Measures* such as smaller subscription contracts to support novel antimicrobial drug developers that need a financial lifeline.