

The PASTEUR Act

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 infections becomes much harder, increasing risk of disease spread, severe illness, and death.

Why is Antimicrobial Resistance an Issue of Concern? The rapid emergence of resistant antimicrobials has resulted primarily from 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 across the globe. In the United States, more than 2.8 million antibiotic-resistant infections occur each year, resulting in over 35,000 deaths. A 2022 CDC special report found that the United States reversed its progress on AMR during the COVID-19 pandemic in 2020 and antimicrobial-resistant infections and deaths increased in hospitals by at least 15 percent.

As of 2023, the World Health Organization estimates that 1 in 6 bacterial infections are resistant to antibiotics. 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, and recent analyses estimate that the broader impact of superbugs on the U.S. economy could reach tens of billions of dollars each year.

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, creating a severe market failure. In recent years, many of the innovative antibiotic companies working to develop new antimicrobials have filed for bankruptcy and stopped producing these innovative antibiotics completely. The Center for Global Development estimates that investing \$63 billion per year into antibiotic research and access globally would generate \$1.7 trillion in annual economic and health benefits.

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. The PASTEUR Act would invest \$6 billion to establish a subscription-style model which would offer antibiotic developers a predictable stream of payments, delinked from sales volume, encouraging innovation and ensuring our health care system is prepared to treat resistant infections.

The PASTEUR Act Would:

- ***Establish a Federal Subscription Model*** that provides annual payments to developers of eligible antibiotics and antifungals. Contract values range from \$75 million to \$300 million per year, with terms up to 10 years or until a generic or biosimilar enters the market. The annual predictable, set level of payment for a given product would be reduced by net revenues the manufacturer makes from its product each year, ensuring no more federal support is provided than necessary to provide a predictable return on investment.
- ***Use a Transparent Scoring System*** to determine eligibility and contract value, rewarding products that address urgent threats and unmet medical needs and that demonstrate major clinical and public health benefits.
- ***Establish a Critical Need Antimicrobial Advisory Group***, consisting of infectious disease physicians, antimicrobial resistance and R&D experts, and patient advocates to guide the design of the program.
- ***Terms & Conditions*** of the subscription contracts would require developers to ensure commercial availability, reliable supply, public reporting of resistance data, implementation of stewardship and education plans, adherence to manufacturing and environmental best practices, and completion of post-market studies.
- ***Support Antimicrobial Stewardship and Surveillance*** by funding pilot programs for expanding stewardship efforts, including in outpatient settings (e.g. urgent care, retail clinics) and build on existing frameworks to enhance data collection on antibiotic use, resistance, and diagnostics through the CDC's National Healthcare Safety Network and other surveillance systems.