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Is the antibiotic pipeline running dry?

Kadiyali Srivatsa*

Weldon School of Biomedical Engineering, Purdue University, USA

***Correspondence to:** Kadiyali Srivatsa, Weldon School of Biomedical Engineering, Purdue University, USA, E-mail: je medifix@gmail.comrome@unn.edu.ng

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Introduction

Antibiotics have been the bedrock of modern medicine since the discovery of penicillin in 1928. They transformed once-lethal infections into manageable conditions and enabled complex medical procedures like organ transplants and chemotherapy. However, the efficacy of antibiotics is under siege due to the relentless rise of antimicrobial resistance (AMR). As bacteria evolve to evade existing drugs, the urgent need for new antibiotics grows. Yet, the development pipeline for novel antibiotics remains alarmingly sparse. This article explores the current state of antibiotic innovation, the challenges facing pharmaceutical development, and emerging strategies to revitalize the pipeline [1].

Organizations like CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) are working to bridge the funding gap in early-stage antibiotic development. CARB-X supports a diverse portfolio of products, including antibiotics, vaccines, diagnostics, and non-traditional therapies. New funding models are also being proposed, such as "subscription-based" payments where governments pay pharmaceutical companies for access to antibiotics regardless of usage. This decouples revenue from sales volume and incentivizes innovation while preserving stewardship. AMR is a global health crisis responsible for approximately 1.2 million deaths annually, with projections suggesting this number could reach 10 million by 2050 if no effective action is taken. Common infections such as urinary tract infections (UTIs), pneumonia, and bloodstream infections are increasingly resistant to first-line treatments. The World Health Organization (WHO) has identified a list of priority pathogens—bacteria that pose the greatest threat to human health due to their resistance profiles [2].

According to the WHO's 2024 report on antibacterial development, the clinical pipeline has grown modestly—from 80 agents in 2021 to 97 in 2023. However, only 32 of these target WHO priority pathogens, and just 12 are considered truly innovative. Alarmingly, only four of these show activity against "critical" pathogens like carbapenem-resistant *Acinetobacter baumannii* and *Pseudomonas aeruginosa*. Since July 2017, only 13 new antibiotics have received marketing authorization, and just two represent new chemical classes. This underscores the scientific and technical difficulty of discovering novel antibiotics that are both effective and safe [3].

Several factors contribute to the stagnation in antibiotic development: Bacteria have complex defense mechanisms, and discovering compounds that can bypass these defenses without harming human cells is difficult. Many promising molecules fail in early testing due to toxicity or lack of efficacy. Antibiotics are typically used for short durations and are often reserved for last-resort cases to prevent resistance. This limits their market potential. As Kevin Outterson, executive director of CARB-X, explains: "New antibiotics are used sparingly to prevent resistance. That is wonderful advice for public health, but for the company with a new antibiotic, that spells bankruptcy". The path to approval is long and expensive. Clinical trials for antibiotics targeting resistant pathogens require specialized patient populations, making recruitment and study design challenging [4].

Approved by the FDA in April 2024, this is the first new oral antibiotic in two decades for uncomplicated UTIs. It targets *E. coli*, *Proteus mirabilis*, and *Staphylococcus saprophyticus*, offering a narrow-spectrum alternative with fewer side effects. Approved in October 2024, this oral penem antibiotic is effective against extended-spectrum beta-lactamase (ESBL) producing *E. coli*

and *Klebsiella pneumoniae*. It addresses a critical gap in oral treatment options for resistant UTIs. These approvals demonstrate that innovation is possible, but they also highlight how rare such breakthroughs are. To overcome the limitations of conventional antibiotics, researchers are exploring alternative strategies: Viruses that infect and kill bacteria, offering targeted therapy with minimal impact on the microbiome. Compounds that disarm bacteria rather than kill them, reducing selective pressure for resistance. Strategies that restore healthy microbial balance to outcompete pathogenic strains. Enhancing host defenses to clear infections more effectively. While promising, these approaches face regulatory and clinical challenges, including standardization, delivery mechanisms, and long-term safety [5].

Conclusion

The antibiotic pipeline is not entirely dry—but it is dangerously thin. The slow pace of innovation, coupled with rising resistance, threatens to undo decades of medical progress. Addressing this crisis requires a multifaceted approach: incentivizing pharmaceutical innovation, supporting non-traditional therapies, reforming regulatory frameworks, and ensuring global access. Ironically, while overuse drives resistance, many people in low- and middle-income countries lack access to essential antibiotics. Balancing stewardship with equitable access is a major challenge. Innovative antibiotics must be deployed judiciously to preserve their efficacy, but also made available to those in need. Antibiotics are a societal good, not just a commercial product. Their value lies not in the volume sold, but in the lives saved. Reviving the pipeline is not just a scientific imperative—it's a moral one.

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