

Without Effective and Novel Antibiotics Resistant Infections Threaten Us All

THE MARKET FOR ANTIBIOTICS IS BROKEN

Combating the growing threat of antimicrobial resistance (AMR) requires generation of innovative antibiotics, but low expected return on investment limits commercial development. This issue is due in part to challenges with generating antibiotics with new mechanisms, small clinical trial populations, and limited diagnostic capabilities. New antibiotics also face unique market challenges:

1. Antibiotic stewardship programs safeguard public health but restrict sales volume.¹
2. Constrained hospital and pharmacy budgets encourage health care facilities and prescribers to first use the least expensive, generally generic, antibiotic option.
3. Typical antibiotic clinical trial designs do not provide comparative effectiveness evidence that justifies increased reimbursement.
4. Current payment approaches don't recognize the additional health benefits of novel antibiotics, such as the avoidance of infection among those adjacent to infected individuals.²

Because new antibiotics face these persistent challenges, incentives are needed to sustain the antibiotic pipeline. Push incentives are intended to encourage antibiotic development by reducing financial barriers or providing funding during pre-clinical and clinical stages. Funds from CARB-X and BARDA are push incentives. Pull incentives encourage antibiotic development by providing a financial reward following an antibiotic's approval. Pull incentives might provide a supplement to revenue or de-link payment from sales volume. The US lacks adequate pull incentives to sustain a robust antibiotic arsenal.

CURRENT LEGISLATIVE PROPOSALS

Congress can consider enacting pull incentives like the DISARM and PASTEUR Acts—

DISARM would reimburse antibiotics independently of Medicare's DRG-based bundled payments, increasing product revenue, but preserving fee-for-service payments linked to volume use.³

PASTEUR would create a mechanism for developers to enter into subscription contracts that guarantee between \$750M and \$3B for critical need antibiotics, and developers would commit to maintaining product availability and supporting appropriate antibiotic use.^{4,5}

WHY PAYMENT REFORMS ARE NEEDED FOR NOVEL ANTIBIOTIC AVAILABILITY AND ACCESS

The fundamental problem with most antibiotic reimbursement is that it occurs under a fee-for-service, volume-based payment structure. Fee-for-service payments do not capture the population health benefits that effective antibiotics offer. For this reason, Duke-Margolis and others are calling for reforms that incentivize the development, availability, and appropriate use of qualifying antibiotics.⁶

Population-based payments, like subscription models, can potentially improve antibiotic development, payment, and stewardship.⁶⁻⁸ As a central tenet, such models recognize that antibiotics provide value beyond that reflected by the inexpensive prices the market currently demands. The United Kingdom is piloting such a model, which will delink antibiotic reimbursement from volume use.⁹

Population-based payment reforms are being implemented in other parts of health care, but are not being tested for new antibiotics in the United States. Implementation of these reforms will create a sustainable market for innovative antibiotics and will result in a vibrant antibiotic ecosystem, ensuring access to critical, life-saving antibiotics for all.

References

1. Core Elements of Hospital Antibiotic Stewardship Programs. Centers for Disease Control and Prevention. Published February 7, 2020. Accessed May 1, 2020. <https://www.cdc.gov/antibiotic-use/core-elements/hospital.html>
2. Verma S. Securing Access to Life-Saving Antimicrobial Drugs for American Seniors. CMS Blog. Published August 6, 2019. Accessed April 30, 2020. <https://www.cms.gov/blog/securing-access-life-saving-antimicrobial-drugs-american-seniors>
3. Roskam PJ. *Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act of 2015.*; 2015. Accessed April 29, 2020. <https://www.congress.gov/114/bills/hr512/BILLS-114hr512ih.pdf>
4. Bennet M. *The Pioneering Antimicrobial Subscriptions To End Up Surging Resistance Act of 2020.*; 2020.
5. Bennet M. Senator Michael Bennet Letter to Speaker Pelosi and Leader Schumer. Published online April 7, 2020. Accessed July 21, 2020. https://www.bennet.senate.gov/public/_cache/files/b/d/bd4f3264-6222-499f-955b-7987a38e4d5e/BBD575913B100CCC0DBDDA622C898670.bennet-letter-on-colorado-priorities.pdf
6. Schneider M, Daniel GW, Harrison NR, McClellan MB. *Delinking US Antibiotic Payments through a Subscription Model in Medicare.*; 2020:13. https://healthpolicy.duke.edu/sites/default/files/atoms/files/margolis_subscription_model_14jan2020.pdf
7. Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's efforts to foster discovery and development of new tools to fight antimicrobial-resistant infections. U.S. Food and Drug Administration. Published June 16, 2018. Accessed April 29, 2020. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-efforts-foster-discovery-and-development-new-tools>
8. Daniel GW, McClellan MB, Schneider M, Qian J, Lavezzari G, de Graffenreid E. *Value-Based Strategies for Encouraging New Development of Antimicrobial Drugs.* Duke-Margolis Center for Health Policy; 2017. https://healthpolicy.duke.edu/sites/default/files/atoms/files/value-based_strategies_for_encouraging_new_development_of_antimicrobial_drugs.pdf
9. *Developing and Testing Innovative Models for The Evaluation and Purchase of Antimicrobials (Activity 1: Evaluation Framework).* National Institute for Health and Care Excellence