The Antibiotic Development Challenge
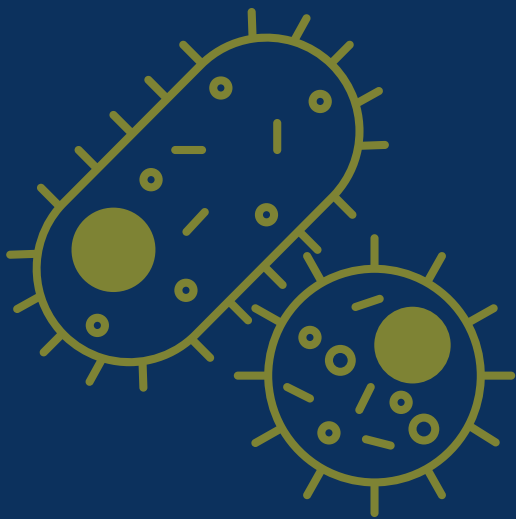
The Role of the US Policymaker

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Executive Summary

Antimicrobial resistance (AMR) is a natural phenomenon by which pathogenic bacteria or other microbes incrementally become less susceptible to medical treatments, such as antibiotics. The excess or inappropriate use of these treatments has driven the problem of resistance, and the lack of proper market infrastructure for antibiotic development has exacerbated the problem. Without effective antimicrobial treatments or the introduction of novel antimicrobial treatments, we are quickly losing the ability to easily treat infections. Furthermore, and quite frighteningly, treatment of these infections may become impossible in the not-so-distant future.

To keep up with microbial adaptation, policy action must take place. We must introduce a new framework for antimicrobial development and production to counter the market inefficiencies and barriers that have landed us in our current situation. A new framework for antimicrobial research and development must build on two ideas: (1) fostering innovation and (2) incentivizing stewardship. Fostering innovation can be accomplished by creating a market that is equally competitive and collaborative.

Subject-matter experts agree that antimicrobial market reform can be accomplished through incentive-based policies that delink the profits received from researching and developing a treatment from the actual sales volumes of the treatment (Global Coalition on Aging 2018). Incentive models that accomplish this goal will not only foster innovation in antimicrobial research; they will also promote the accurate and conservative use of such treatments. Of specific note are subscription-style incentive models, which provide a product to healthcare organizations that are then able to discern when it is most appropriate to use the medication.

The Scope of the Problem

The longer an intervention for AMR is delayed, the harder it will become to implement.

Currently, AMR is a global problem that burdens low- and middle-income countries (LMICs) more than countries that have stronger infrastructures and better access to resources. But as the number of effective treatments we have in our arsenal diminishes, so will the protection found in being a citizen of a resource-rich nation.

The growth and spread of AMR are why action on a policy level is necessary. The time-sensitive nature of the issue determines how much money it will take to solve the problem and how feasible it will be to treat future infections.

The role of a policymaker is vital to the success of any intervention to improve antimicrobial development. Implementing sustainable policy will bring positive and evidence-based change, which, most important, will represent the best interests of the public.

From a market perspective, the status quo of how antibiotics are developed and distributed contributes to the problem of AMR. Creating and executing constructive policy-level change is the best course to correct the deficiencies in the current antimicrobial market, and immediate change is necessary to prevent the further deterioration of effective medications.

Current Policies and Alternatives

As of this writing, no adopted national policy within the United States explicitly encourages and incentivizes the development and concurrent appropriate use of novel antimicrobial classes.

Pull incentives. Pull incentives, such as the United Kingdom's subscription-style model or the United States' proposed PASTEUR Act, attempt to reward the development of new antibiotics that have proven to be viable treatments and fulfill a healthcare need (Outterson and Rex 2023; Dall 2023). Pull incentives accomplish this by essentially reducing the risk of a poor return on investment (ROI) through mechanisms that evaluate the drug's overall value as a treatment and thus de-link the reward of producing the drug from sales.

Push incentives. Push incentives, such as the funding supplied by the REPAIR Impact Fund, look to support innovation, research, and the development of novel antibiotics from the very early stages of development to late-stage trials, irrespective of successful access to the market (REPAIR 2023). Push incentives achieve this by lowering developers' costs and risks primarily through financial support in addition to various other means of assistance.

Policy Recommendations

It is imperative that any steps taken to reduce market barriers to antimicrobial development and build a robust policy environment are applied with an open mind. Any policy-level intervention must support innovation and development through financial investment, technical assistance, and institutional backing.

Interventions must reward the market entry of novel and effective treatments that have their value defined not by sales profits but by their effectiveness and distinctiveness within the market. For substantial market change to occur, policies must disconnect antibiotic sales from profits so that companies, investors, and researchers can see an ROI without compromising the effectiveness and value of their new treatment.

Policy must encourage newcomers to the market and support their involvement alongside those who have a longstanding track record of antimicrobial development and production. Policy interventions such as these will cultivate a collaborative yet competitive market environment that will focus less on shares of market sales and more on ingenuity, solution-driven partnership, and retention of product effectiveness.

References

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