Addressing a Growing Public Health Emergency: Antimicrobial Resistance

The COVID-19 pandemic has demonstrated that we need to build a more resilient health care system that is well positioned to prevent and respond to infectious disease outbreaks and other public health crises and natural disasters. Achieving this goal will require addressing the growing threat of antimicrobial resistance (AMR).

The discovery and introduction of antibiotics in the 1940s transformed modern medicine and enabled tremendous progress in health care and life expectancy. Today, this progress is increasingly threatened by AMR. AMR is a natural process that occurs when microorganisms such as bacteria, viruses, fungi and parasites change in ways that make the microorganisms resistant to the medication used to cure the infection. This means the more we use medicines to fight these infections, the more resistance we create.

AMR affects at least 3 million Americans and results in nearly 50,000 deaths annually in the U.S. alone.[1] Globally, antibiotic-resistant infections are directly associated with at least 1.27 million deaths per year, making drug-resistant bacteria a leading cause of death, higher than HIV/AIDS and malaria.[2]

Unfortunately, a growing body of evidence indicates the COVID-19 pandemic has been increasing rates of AMR. As more patients have been hospitalized due to severe COVID-19 infections, often due to worsening respiratory symptoms requiring ventilation, an increasing number of patients have been acquiring secondary bacterial infections that are treated with antibiotics. Trends indicate this has worsened current levels of resistance.[3] A 2022 Centers for Disease Control and Prevention report confirmed cases of resistant, hospital-acquired secondary infections are greater than pre-pandemic levels with a 15% increase in deaths and hospitalizations in 2020 alone. Many hospital-acquired infections became alarmingly more resistant to medicines between 2019 and 2020.[4, 5] And a recent analysis shows that the cost to the U.S. health care system could reach $28.7 Billion by 2035 if all hospital-acquired infections were to become resistant.[6]

To combat this growing threat, we need a consistent and sustainable pipeline of novel antimicrobial medicines to stay ahead of the devastating effects of AMR. Biopharmaceutical researchers are working to develop new and effective treatments to combat AMR. Today, there are nearly 90 medicines in development against drug-resistant infections.[7] These medicines represent more than antibiotics and include innovative, non-traditional antibacterial treatments such as bacteriophage products, live therapeutic products and monoclonal antibodies. However, recent assessments of the pipeline of antibiotics targeting high-risk pathogens also report that though progress has been made, there are still too few potential medicines to meet current and anticipated needs.[8]

The Challenges in Researching, Developing, and Commercializing New Medicines to Combat AMR

In order to manage the growing threat that AMR presents, we need a robust and diverse pipeline of treatments. Experts believe it will be necessary to generate new chemical substances, as well as a better understanding of how to overcome the most difficult-to-treat infections in order to make progress on new research and development.

Unfortunately, several obstacles, including the costs and risks associated with researching and developing new antimicrobials and other factors that limit the commercial viability for those that reach the market, stand in the way of needed innovation. Collectively, these challenges make it harder for biopharmaceutical research companies to recoup the substantial costs of R&D.

Developing new medicines is a long, complex and risky process. Among antibiotics, this process is fraught by even more uncertainty and can take anywhere from 10 to 20.5 years to develop a single new medicine. In fact, in existing classes of antibiotics in preclinical development, just one in 15 will ultimately be approved and reach patients. And among new classes of antibiotics, these odds are even slimmer, with just one in 30 ultimately obtaining FDA approval.[9]

The fundamental problem with establishing a robust pipeline for new medicines to target antimicrobial resistance is, unlike other medicines, the market is intentionally limited by design. That is because in order to slow the inevitable process of resistance, new medicines must be used only in a limited set of circumstances and in only in the most necessary cases. These limitations make it particularly challenging for biopharmaceutical companies to not only attract sufficient investment to fund R&D but to recoup those costs once an antimicrobial reaches the market.

Unfortunately, our current reimbursement system also reinforces poorly aligned incentives which discourage appropriate use of new antimicrobials and instead favor older medicines that have been around for decades but may be less effective in meeting current AMR threats. That is because newer antimicrobial medicines are often more expensive than older ones, and our bundled payment system creates financial disincentives for hospitals to prescribe these newer medicines, even when they may be more appropriate to treat drug-resistant infections.

As a result of these challenges, in recent years a number of biotechnology companies have declared bankruptcy or exited this space, including those who have successfully developed new antimicrobials.[10] In fact, while 15 new antimicrobials were approved over the past decade, a third of the companies behind those medicines subsequently filed for bankruptcy and exited the field.[11] We need to urgently fix these dynamics if we want to ensure we have the medicines we will need for the next public health emergency.

Addressing AMR is Key to Future Preparedness

As we look to the future and the need to address the growing threat of AMR, public policies are needed to create a more sustainable environment for antimicrobial R&D and commercialization and ensure a robust pipeline for future treatments.

To overcome the market's failure to drive innovation for new antimicrobial medicines, innovative partnerships and initiatives within and between the public and private sectors have evolved. In fact, the biopharmaceutical industry is taking action through the AMR Action Fund.[12] This fund aims to bring two to four new antimicrobials to market by 2030 by investing more than $1 billion in smaller biotech companies and focusing on innovative medicines that address the highest priority public health needs.

In addition, policymakers should support the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTUER) Act. This Act would offer "subscription" contracts to manufacturers to provide full access for federal healthcare programs to antimicrobial products and incentivize companies to develop these medicines. Additionally, payment reforms addressing misaligned incentives in the inpatient bundled payment system in Medicare that encourage use of low-cost generics over antibiotics would also make a meaningful difference. Comprehensive policy reforms such as these are critical steps to address this preventable crisis.

PhRMA and our members are committed to bolstering pandemic preparedness and health care resiliency to make sure our country and American patients are stronger, healthier and better prepared for the next public health emergency. Having a robust pipeline of medicines to address AMR is a key part of that preparedness. If we all work together, we can be prepared for the next public health emergency by ensuring a sustainable pipeline for new antimicrobials for this crisis as well as those in years to come.

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