



July 11, 2023

The Honorable Ed Markey  
Chairman  
Senate Committee on Health, Education,  
Labor, and Pensions  
Subcommittee on Primary Health and  
Retirement Security  
Washington, D.C. 20515

The Honorable Roger Marshall, MD  
Ranking Member  
Senate Committee on Health, Education,  
Labor, and Pensions  
Subcommittee on Primary Health and  
Retirement Security  
Washington, D.C. 20515

Dear Chairman Markey and Ranking Member Marshall:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments in advance of your hearing, “Superbugs: The Impact of Antimicrobial Resistance on Modern Medicine.”

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation’s healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. We are uniquely positioned to address innovation comprehensively from all perspectives in the healthcare industry.

HLC thanks you for focusing on the critical issue of antimicrobial resistance (AMR) and urges Congress to enact S.1355/H.R.2940, the “Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act of 2023,” as an important step in this effort.

AMR poses a serious threat in the U.S. and around the world. AMR is the leading cause of death globally. It is estimated to have directly caused at least 1.27 million deaths and contributed to another 5 million deaths in 2019.<sup>1</sup> In the U.S., more than 2.8 million antimicrobial-resistant infections occur and are responsible for more than 35,000 deaths each year.<sup>2</sup> Because emergencies often exacerbate the AMR crisis, measures to address AMR should be incorporated into broader emergency preparedness efforts. For example, the COVID-19 pandemic caused a surge in hospitalizations and ventilator use. As a result, U.S. hospitals

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<sup>1</sup> Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis, The Lancet, (January 19, 2022), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext).

<sup>2</sup> National Infection & Death Estimates for Antimicrobial Resistance, Centers for Disease Control and Prevention (December 13, 2021), <https://www.cdc.gov/drugresistance/national-estimates.html>.

experienced a 15% increase in AMR infections and deaths in 2020.<sup>3</sup> Hurricanes and other natural disasters also increase the spread of infections. AMR should also be considered in bioterror preparedness, as agents used by bioterrorists may be genetically engineered to resist current therapeutic antimicrobials.

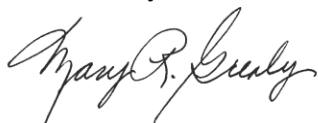
Despite tremendous need, there is still a lack of progress in the development of critical new antibacterial therapies to tackle the threat of AMR. Of the 12 antibiotics that have been approved since 2017, 10 belong to existing classes with established mechanisms of AMR. In 2021, the World Health Organization (WHO) reported only 27 new antibiotics in clinical development against priority pathogens, down from 31 products in 2017. Of the 27, only six products meet at least one of the WHO's criteria for innovation – which include absence of known cross-resistance, new target, new mode of action, and/or new class – and only two acts against critical gram-negative bacterial pathogens, which are multidrug-resistant and have few other treatment options.<sup>4</sup>

This stagnant innovation not only fails to meet the serious current threats AMR poses, but we can expect the consequences to modern healthcare to continue to grow in the future if no action is taken. It is important that new incentives, including post-market incentives, are put in place to help provide the economic certainty needed to bring these critical medicines to the market. HLC supports the innovative subscription model proposed in the PASTEUR Act. Payment modes based on volume only exacerbate the risks of AMR, as over-usage of antibiotics is a major driver of resistance. Under the PASTEUR Act, the federal government can enter into contracts with innovators to pay for a reliable supply of novel antimicrobials with payments that are decoupled from the volume of antimicrobials used.

This delinked approach is similar to Project Bioshield, which provides multi-year funding to support procurement of medical countermeasures (MCM) for national security. Like MCM, antimicrobials have a very limited commercial market. The PASTEUR Act will provide antimicrobial innovators with a more predictable return on investment necessary to revitalize the antimicrobial pipeline.

Thank you for your efforts to address the AMR crisis. HLC looks forward to working with you on our shared priorities. If you have any questions, please do not hesitate to contact Debbie Witchey at (202) 449-3435 or [dwitchey@hlc.org](mailto:dwitchey@hlc.org).

Sincerely,



Mary R. Greal  
President

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<sup>3</sup> COVID-19, U.S. Impact on Antimicrobial Resistance, Centers for Disease Control and Prevention, (2022), <https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf>.

<sup>4</sup> 2021 Antibacterial Agents in Clinical and Preclinical Development: An Overview and Analysis, The World Health Organization, (May 27, 2022), <https://www.who.int/publications/i/item/9789240047655>.