



April 13, 2023

The Honorable Tammy Baldwin
Chair
Subcommittee on Labor-HHS-Education
Senate Appropriations Committee
Washington, D.C. 20510

The Honorable Shelley Moore Capito
Ranking Member
Subcommittee on Labor-HHS-Education
Senate Appropriations Committee
Washington, D.C. 20510

Dear Chairwoman Baldwin and Ranking Member Moore Capito:

As you begin consideration of Fiscal Year (FY) 2024 Labor, Health and Human Services, Education, and Related Agencies appropriations legislation, we ask that you continue to provide robust funding for a comprehensive federal response to antimicrobial resistance (AMR). This silent epidemic is only getting worse, and the current state of the AMR pharmaceutical market does not have sustainable incentives to spur innovation or maintain market access. Federal support – in addition to authorizing legislation – will be needed to change our current trajectory and ensure patients have access to life-saving antibiotics.

AMR is increasing the risk of death due to unmanageable infections. In 2019, it killed over 1.2 million people it led to 4.95 million deaths worldwide making it the third leading cause of death after cardiovascular disease and cancer.¹ Latest available data shows that drug-resistant infections sicken at least 2.8 million and kill at least 35,000 people annually across the country.² Sadly, some of these deaths are related to AMR rendering lifesaving medicines ineffective. Many medical procedures rely on antibiotics in a treatment course, some of which include chemotherapy, transplantation, caesarian sections, and treatment for secondary bacterial infections in patients with viral respiratory infections. Chemotherapy, for example, is part of a standard of care that is highly utilized to save patients with different types of cancer, yet AMR infections are a primary or associated cause of death in 50 percent of this patient population.³ On top of this, AMR has a disproportionate impact on certain communities due to variance in risk of exposure, susceptibility to infection, or treatment received.⁴

If pharmaceutical innovation is not achieved to combat AMR, by 2050, antibiotic resistant infections will be the leading cause of death – surpassing cancer – and could cost the world \$100 trillion. Already, drug-resistant infections in the U.S. is skyrocketing.⁵ Antimicrobial-resistant infections and

¹ Murray, Christopher JL, Kevin Shunji Ikuta, Fablina Sharara, Lucien Swetschinski, Gisela Robles Aguilar, Authia Gray, Chieh Han et al, "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis," *The Lancet* 399, no. 10325 (2022): 629-655, <https://www.sciencedirect.com/science/article/pii/S0140673621027240>.

² U.S. Centers for Disease Control and Prevention (CDC), Antibiotic Resistance Threats in the United States: 2019, <https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf>.

³ Nanayakkara, Amila K., Helen W. Boucher, Vance G. Fowler Jr, Amanda Jezek, Kevin Outterson, and David E. Greenberg, "Antibiotic resistance in the patient with cancer: Escalating challenges and paths forward," *CA: a cancer journal for clinicians* 71, no. 6 (2021): 488-504, <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21697>.

⁴ CDC, Health Equity and Antibiotic Resistance, accessed March 13, 2023, <https://www.cdc.gov/drugresistance/pdf/Health-Equity-Antibiotic-Resistance-FS-508.pdf>.

⁵ CDC, COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report, 2022, <https://www.cdc.gov/drugresistance/covid19.html>.

deaths rose 15 percent in 2020 due to the COVID-19 pandemic, wiping out progress made in 2012-2017 to lower deaths as a result from AMR.

The U.S. will bear a substantial economic burden if this trajectory remains on course. Therefore, we ask your Committee to consider providing continued funding for several programs to help combat AMR and mitigate this escalating health crisis.

Assistant Secretary for Preparedness and Response (ASPR)

- **Biomedical Advanced Research and Development Authority, Broad Spectrum Antimicrobials and CARB-X:** The BARDA broad spectrum antimicrobials program and CARB-X leverage public-private partnerships to develop innovative products that prevent, detect, and treat resistant infections. These efforts have led to new FDA approved antibiotics that improve patient outcomes. Despite this progress, the pipeline of new antibiotics in development is insufficient to meet patient needs and robust funding is needed to prevent a post-antibiotic era.⁶ The imminent collapse of the antibiotic market is exacerbating this threat, and small companies that are responsible for nearly all current antibiotic innovation are facing bankruptcy because factors unique to antibiotics, including the need for judicious use, make it challenging for companies to earn a return on investments in antibiotic research and development. BARDA has the potential to play a pivotal role in advancing new innovative products.
- **Project BioShield Special Reserve Fund (SRF), Broad Spectrum Antimicrobials:** The Project BioShield SRF is positioned to support the response to public health threats, including AMR. BARDA and NIAID efforts have been successful in helping companies bring new antibiotics to market, but those companies now struggle to stay in business and two filed for bankruptcy in 2019, with others on similar trajectories. In December 2019, SRF funds supported a contract for a company following approval of its antibiotic—a phase in which small biotechs that develop new antibiotics are particularly vulnerable. In October 2022, a second contract was awarded through Project BioShield to support the development and procurement of a novel antimicrobial product that addresses multi-drug resistant infections and supports national preparedness efforts.

Centers for Disease Control and Prevention

- **Antibiotic Resistance Solutions Initiative:** Continued robust funding to bolster antibiotic stewardship across the continuum of care, double state and local grant awards, expand the AR Laboratory Network globally and domestically to strengthen the identification, tracking and containment of deadly pathogens, support AMR research and epicenters, and increase public and health care professional education and awareness. Congress's investments in the program are making a difference but additional resources are necessary to escalate the fight against AMR.
- **National Healthcare Safety Network (NHSN):** Continued robust funding is needed to modernize and automate NHSN to alleviate reporting burden and speed access to actionable data. Funding would bolster data collection on antibiotic use and resistance in healthcare facilities, expand COVID-19 reporting, and provide technical support for more than 65,000 users of NHSN.
- **Advanced Molecular Detection Initiative:** Continued robust funding would ensure continued innovation in the detection and tracking of existing and emerging pathogens. Funding would also enable federal, state, and local public health laboratories to expand the use of pathogen genomics,

⁶ Biotechnology Innovation Organization, The State of Innovation in Antibacterial Therapeutics, by David Thomas, CFA and Chad Wessel, February 2022, <https://www.bio.org/sites/default/files/2022-04/BIO-Antibacterial-Report-2022.pdf>.

sustain important partnerships with academic research institutions, and bolster training to ensure integration of genomics into infectious disease surveillance and response, including resistant pathogens.

- **Division of Global Health Protection:** Continued robust funding is needed to improve global capacity to identify and stop threats before they reach U.S. soil as well as address growing drug resistance in low-income countries. Specifically, funding would enhance infectious disease surveillance, strengthen laboratory capacity, train health care workers and epidemiologists and support emergency operations centers. CDC experts provide technical assistance to 30 countries and work to detect resistant threats; prevent and contain resistance germs; and improve antibiotic use.

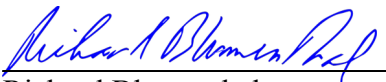
National Institutes of Health (NIH)

- **National Institute of Allergy and Infectious Diseases:** Full funding would support the training of new investigators, and strengthen our nation's clinical trial infrastructure to boost preparedness. NIAID also helps to enhance basic, translational, and clinical research on mechanisms of resistance, therapeutics, diagnostics, and support the development of a clinical trials network to reduce barriers to research on difficult-to-treat infections.

The COVID-19 pandemic was a sobering reminder of why we must prioritize agencies like BARDA to combat infectious diseases, including AMR, through Project BioShield. We are encouraged that the President's Budget Request for FY 2024 prioritizes AMR in multiple ways, including a proposal to strengthen antibiotic research and development through the use of federal contracts that delink payments for novel antimicrobials from their use. We urge you place high priority on continued robust funding for AMR as the FY2024 appropriations process moves forward.

Thank you for your consideration of this request.

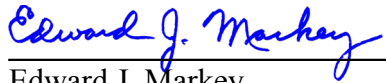
Sincerely,



Richard Blumenthal
United States Senator



Roger W. Marshall
Member of Congress



Edward J. Markey
United States Senator



Christopher S. Murphy
United States Senator



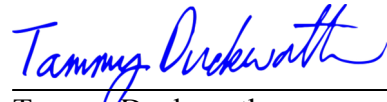
Sherrod Brown
United States Senator



Elizabeth Warren
United States Senator



Maria Cantwell
United States Senator



Tammy Duckworth
United States Senator



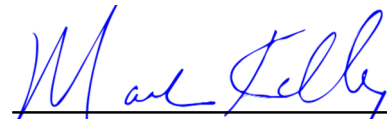
Catherine Cortez Masto
United States Senator



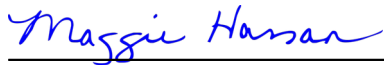
Cory A. Booker
United States Senator



Michael F. Bennet
United States Senator



Mark Kelly
United States Senator



Margaret Wood Hassan
United States Senator



Christopher A. Coons
United States Senator



Kirsten Gillibrand
United States Senator



Gary C. Peters
United States Senator



Debbie Stabenow
United States Senator



M. Michael Rounds
United States Senator



Sheldon Whitehouse
United States Senator



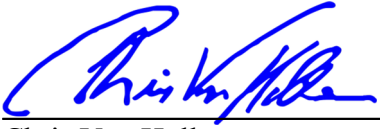
Tina Smith
United States Senator



Dianne Feinstein
United States Senator



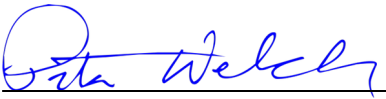
Alex Padilla
United States Senator



Chris Van Hollen
United States Senator



John Hickenlooper
United States Senator



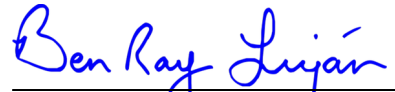
Peter Welch
United States Senator



Amy Klobuchar
United States Senator



Kyrsten Sinema
United States Senator



Ben Ray Lujan
United States Senator