Congress of the United States

Washington, DC 20510

April 26, 2022

The Honorable Rosa DeLauro Chair Subcommittee on Labor, Health and Human Services, and Education Appropriations Committee on Appropriations Washington, DC 20515 The Honorable Tom Cole Ranking Member Subcommittee on Labor, Health and Human Services, and Education Appropriations Committee on Appropriations Washington, DC 20515

Dear Chairwoman DeLauro and Ranking Member Cole:

As you begin consideration of Fiscal Year 2023 Labor, Health and Human Services, Education, and Related Agencies (LHHS) appropriations legislation, we ask that you increase support for a comprehensive federal response to antimicrobial resistance (AMR), commensurate with the threat AMR poses to patient care, public health, and preparedness. The Washington Post editorial called AMR a shadow pandemic to COVID-19. We must apply lessons learned from the pandemic to help improve our defenses against this escalating health crisis. We are encouraged that the President's Budget Request for FY23 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.

Antimicrobial resistance is rendering lifesaving medicines ineffective jeopardizing medical procedures that rely upon antibiotics, including cancer chemotherapy, transplantation, caesarian sections, other surgeries, treatment of serious wounds and burns, and care of complex patients — such as those with COVID-19 who develop secondary infections. Additionally, According to CDC, AMR has a disproportionate impact on certain communities due to variance in risk of exposure, susceptibility to infection or treatment received. Rates of several serious antibiotic resistant infections, including community-associated MRSA, have a higher incidence in Black populations. In the U.S., Black patients are also twice as likely to die from complications of severe infections driven by antibiotic resistance, including sepsis, than white patients.

Drug-resistant infections sicken at least 2.8 million and kill at least 35,000 people annually in the U.S. Infections are a primary or associated cause of death in 50% of patients with cancer, as AMR can make these infections difficult or impossible to treat. A January 2021 study by the Centers for Disease Control and Prevention (CDC) and the University of Utah estimates that the national healthcare costs associated with infections from six of the 18 most alarming antibiotic resistance threats to be more than \$4.6 billion annually. Antibiotics are central to preparedness, as nearly any mass casualty event can be significantly complicated by secondary infections. From March-September 2020, there was a 24% increase in hospital-onset multidrug resistant infections associated with COVID-19 surges In 2019, AMR killed over 1.2 million people and played a part in 4.95 million deaths. If we do not act now, by 2050 antibiotic resistant infections will be the leading cause of death - surpassing cancer - and could cost the world \$100 trillion.

It is estimated that 30 to 50 percent of antibiotic prescriptions are inappropriate. Preserving the effectiveness of antibiotics, by reducing overuse and misuse, must be prioritized. The pipeline of new

antibiotics in development is insufficient to meet patient needs. 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.

Congress must fully support the funding necessary to significantly reduce the burden of AMR, including:

Centers for Disease Control and Prevention

- Antibiotic Resistance Solutions Initiative (\$397 million): \$397 million in funding for ARSI. The President's budget proposal includes \$197 million in discretionary funding and \$200 million each year in mandatory funding from FY2023-2028 (as part of the larger pandemic preparedness request), for a total of \$397 million in FY2023. This is needed to expand 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 (\$100 million):** Full 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 (\$175 million): 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, 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 (\$454.6 million): Full 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.

Assistant Secretary for Preparedness and Response (ASPR)

- **Biomedical Advanced Research and Development Authority, Broad Spectrum Antimicrobials and CARB-X (\$300 million):** 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 full funding is needed to prevent a post-antibiotic era.
- **Project BioShield Special Reserve Fund, Broad Spectrum Antimicrobials (\$200 million):** 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.

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. Full funding is needed to expand this approach to better support the antibiotics market.

National Institutes of Health (NIH)

• National Institute of Allergy and Infectious Diseases (\$6.7 billion/\$585 million for AMR research): Funding at this level would allow NIAID to address AMR while conducting its broader role in supporting infectious diseases research. Increased funding would support the training of new investigators; strengthen clinical trial infrastructure to boost preparedness; enhance basic, translational, and clinical research on mechanisms of resistance, therapeutics, vaccines and diagnostics; and support the development of a clinical trials network to reduce barriers to research on difficult-to-treat infections.

There is an urgent need for continued action on antimicrobial resistance. We urge you place high priority on increased funding for AMR as the FY2023 appropriations process moves forward. Thank you for your consideration of this request.

Sincerely,

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