The Honorable Rosa DeLauro U.S. House of Representatives 2413 Rayburn House Office Building Washington, DC 20515

The Honorable Sanford Bishop, Jr. U.S. House of Representatives 2407 Rayburn House Office Building Washington, DC 20515

The Honorable Barbara Lee U.S. House of Representatives 2470 Rayburn House Office Building Washington, DC 20515 The Honorable Tom Cole U.S. House of Representatives 2207 Rayburn House Office Building Washington, DC 20515

The Honorable Andy Harris U.S. House of Representatives 2334 Longworth House Office Building Washington, DC 20515

The Honorable Hal Rogers U.S. House of Representatives 2406 Rayburn House Office Building Washington, DC 20515

April 27, 2022

Dear Chairs and Ranking Members of the Labor-HHS-Education, Agriculture, and State and Foreign Operations Appropriations Subcommittees:

The undersigned organizations, representing clinicians, scientists, patients, public health, animal agriculture and the pharmaceutical and diagnostics industries, urge you to significantly increase federal funding for domestic and global antimicrobial resistance (AMR) programs. We call for a comprehensive One Health approach that encompasses human, animal and environmental health with increased funding for surveillance, prevention, stewardship, research and innovation.

Antibiotic resistance is one of the greatest public health threats of our time. Drug-resistant infections sicken at least 2.8 million people and kill at least 35,000 people in the United States each year. Antibiotic resistance accounts for direct health care costs of at least \$20 billion. 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. Globally, resistant infections directly caused 1.27 million deaths in 2019 and played a role in 4.95 million deaths. If we do not act now, antibiotic resistant infections will be the leading cause of death by 2050 and could cost the world \$100 trillion.

AMR has a <u>disproportionate impact</u> 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, are higher incidence in Black populations.

Addressing AMR is central to strengthening our preparedness for future public health emergencies, as patients with respiratory infections, serious wounds or burns, or other conditions requiring hospitalization are all at risk for secondary resistant infections. For example, from March-September 2020, there was a 24% increase in hospital-onset multidrug resistant infections associated with COVID-19 surges.

Unfortunately, the pipeline of new antibiotics in development is insufficient to meet patient needs. Small companies that are responsible for nearly all current antibiotic innovation are struggling to stay in business. Factors unique to antibiotics, including the need for their judicious use, make it challenging

for companies to earn a return on investments in antibiotic research and development. Additionally, new diagnostic tools are needed to help guide appropriate antibiotic use and enable surveillance, and greater investments are needed to support prevention and antibiotic stewardship.

While we are grateful for funding for AMR provided by Congress in FY2022, increased federal appropriations commensurate with the gravity and importance of AMR is urgently needed. We must apply lessons learned from the COVID-19 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 and significant funding increases proposed for CDC AMR activities.

Labor, Health and Human Services, Education and Related Agencies

The Centers for Disease Control and Prevention (CDC)

We recommend \$397 million in funding for the **Antibiotic Resistance Solutions Initiative**. 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.

We recommend \$175 million for the **Advanced Molecular Detection (AMD) Initiative.** Funding would ensure continued innovation in the detection and tracking of existing and emerging resistant 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 AMR surveillance and response.

We recommend \$100 million for the **National Healthcare Safety Network (NHSN).** 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 and provide technical support for more than 65,000 users of NHSN.

We recommend \$991 million overall for the CDC Center for Global Health, including the Division of Global Health Protection (\$454.6 million). Increased resources are needed to improve global health capacity to stop AMR threats before they reach domestic soil as well as address growing drug resistance in developing countries. This Division works to enhance AMR surveillance systems, strengthen laboratory capacity, train health care workers and disease detectives, improve antibiotic use, provide technical assistance to 30 countries and support emergency operations centers. Funding would expand global health capacity address threats in 60 countries.

Assistant Secretary for Preparedness and Response (ASPR)

We recommend funding of \$300 million to support **Broad Spectrum Antimicrobials and CARB-X at the Biomedical Advanced Research and Development Authority (BARDA)**. 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. Despite this progress, the pipeline of new antibiotics in development is insufficient to meet patient needs.

We recommend funding of \$200 million for the **Project BioShield Special Reserve Fund, 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. 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.

National Institutes of Health (NIH)

We recommend \$6.7 billion for the National Institute of Allergy and Infectious Diseases, including \$585 million for AMR Research at NIAID. Funding at this level would allow NIAID to address AMR while carrying out its broader role in supporting infectious diseases research. Increased funding would support the training of new investigators; 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.

Agriculture-FDA

Food and Drug Administration

We recommend \$20 million for Combating Antibiotic Resistance Bacteria efforts at FDA. This level of support is required to advance antibiotic stewardship in animals and to protect antibiotic effectiveness for human and animal populations. With suggested resources, FDA can complete the remaining goals of its 2018 five-year antibiotic stewardship action plan, including strengthening the National Antimicrobial Resistance Monitoring System (NARMS) to make it consistent with One Health principles, and completing work on setting duration limits for veterinary antibiotics. Funding could advance FDA's plan to create and implement a functional and efficient system for collecting antimicrobial use data in animals. Additional funding is needed to assist academic institutions and other partners in the development of veterinary educational materials, and support surveillance capacity-building through FDA's Veterinary Laboratory Investigation and Response Network (Vet-LIRN).

US Department of Agriculture (USDA)

We recommend an increase of \$85 million for antimicrobial resistance priorities at USDA. With most emerging diseases and pandemics originating from animals including food animals, USDA needs more resources to support its work on biodefence to protect both people and animals from resistant infections that are transmitted between humans and animals (zoonosis). An increase of \$25 million for the Animal and Plant Health Inspection Service is needed to strengthen the Zoonotic Disease Management program, which has been chronically underfunded, and to support the and the National Animal Health Laboratory Network (NAHLN). At least \$60 million in additional funding is needed for Research, Education, and Economics to support agricultural research at USDA's Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA) Agriculture and Food Research Initiative (AFRI). These funds will enable USDA investigators and scientists at public universities, veterinary colleges and other research settings to better understand the factors driving the emergence of resistant pathogens, and help producers find new vaccines, antibiotic alternatives and

improved animal management and husbandry practices that can be shared directly with farmers and livestock growers through USDA's Cooperative Extension Service.

State and Foreign Operations

US Agency for International Development (USAID) and Department of State

We recommend \$1 billion for **USAID** global health security efforts to enhance technical assistance to partner countries to prevent and respond to rising rates of AMR in resource-limited settings and strengthen global capacities to prevent and respond to outbreaks while improving U.S. and global health security. We also recommend \$1 billion for **USAID's Tuberculosis Program**, which supports high-quality screening, diagnosis and treatment services for patients affected by multidrug-resistant TB. Finally, we recommend \$2 billion for the **Global Fund to Fight AIDS, TB, and Malaria** to allow continued reductions in malaria and TB and help staunch the growth of drug-resistant forms of these infections including airborne, drug-resistant TB, the biggest infectious disease killer globally in addition to COVID-19.

Conclusion

We greatly appreciate your leadership in providing strong investments in AMR in FY2023. We urge you to continue to place a high priority on AMR to continue making strides to protect patients and public health and spur needed innovation.

Signed,

AdvaMedDx

American Academy of Allergy, Asthma & Immunology

American Academy of Pediatrics

American Association of Bovine Practitioners

American Association of Veterinary Medical Colleges

American Public Health Association

American Society for Microbiology

American Society of Plastic Surgeons

Antibiotic Resistance Action Center, George Washington University

Association for Professionals in Infection Control and Epidemiology

Association of Public Health Laboratories

Association of State and Territorial Health Officials

Biotechnology Innovation Organization

Center for Science in the Public Interest

Clarametyx Biosciences, Inc.

CommonSpirit Health

Cystic Fibrosis Foundation

Emory Antibiotic Resistance Center

Food Animal Concerns Trust

Health Care Without Harm

Hesed Medical Associates

HIV Medicine Association

Infectious Diseases Society of America

Johns Hopkins Center for a Livable Future

Making-A-Difference in Infectious Diseases

Michigan Antibiotic Resistance Reduction Coalition

Microbion Corporation

National Association of Pediatric Nurse Practitioners

Natural Resources Defense Council

Novo Holdings Equity US Inc.

NTM Info & Research

ONCORD, Inc.

One Health Trust

Pediatric Infectious Diseases Society

Peggy Lillis Foundation

Sepsis Alliance

Social Innovation in Drug Resistance Program, Boston University

Society for Healthcare Epidemiology of America

Stuart B. Levy Center for Integrated Management of Antimicrobial Resistance at Tufts

TB Alliance

The American Association of Avian Pathologists

The Gerontological Society of America

The Pew Charitable Trusts

The Renal Physicians Association

Trust for America's Health