

The Honorable Tammy Baldwin
U.S. Senate
Washington, DC 20510

The Honorable Shelly Moore Capito
U.S. Senate
Washington, DC 20510

The Honorable Martin Heinrich
U.S. Senate
Washington, DC 20510

The Honorable John Hoeven
U.S. Senate
Washington, DC 20510

The Honorable Christopher Coons
U.S. Senate
Washington, DC 20510

The Honorable Lindsey Graham
U.S. Senate
Washington, DC 20510

May 14, 2024

Dear Chairs and Ranking Members of the Labor-HHS-Education, Agriculture-Rural Development-FDA, 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. As we look forward to the United Nations High Level Meeting on AMR, providing robust funding to fully implement this comprehensive effort will help the U.S. fulfill its position as a global leader in tackling this growing crisis.

Antimicrobial resistance is one of the greatest public health threats of our time. Drug-resistant infections sicken three million people and kill at least 50,000 people in the United States each year. Just six of the worst resistant pathogens increase U.S. health care costs by \$4.6 billion annually. 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. For example, sepsis, the body's life-threatening response to infection is a dangerous complication of AMR and is the number one cause of death and cost of care (at \$62 billion annually) in U.S. hospitals. 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 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, 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. A 2022 CDC report

found that hospital associated AMR infections and deaths rose 15% in 2020 due to the COVID-19 pandemic, wiping out progress made in 2012-2017 to lower U.S. deaths from AMR.

Safe and effective antimicrobials are essential to enable modern medical advances, including cancer chemotherapy, organ transplantation and other complex surgeries, which all carry a risk of infection. A recent outbreak of drug resistant eye infections causing blindness due to contaminated eye drops demonstrates that serious resistant infections are a threat to us all.

Unfortunately, the pipeline of new antibiotics in development is insufficient to meet patient needs. Small companies that are responsible for nearly all current antibiotic innovations 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.

Increased federal appropriations commensurate with the gravity and importance of AMR are urgently needed to improve our defenses against this escalating health crisis. For FY25, we recommend:

Labor, Health and Human Services, Education and Related Agencies

The Centers for Disease Control and Prevention (CDC)

We recommend \$400 million in funding for the **Antibiotic Resistance Solutions Initiative**. 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 antimicrobial resistance (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 \$60 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 \$1.002 billion overall for the **CDC Center for Global Health**, including the **Division of Global Health Protection** (\$456.4 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 \$330 million to support the **Broad-Spectrum Antimicrobials Program** and **CARB- X** at the **Biomedical Advanced Research and Development Authority (BARDA)**. The BARDA broad spectrum antimicrobials and antifungals 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 and antifungals 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, with others on similar trajectories. In 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. Full funding is needed to expand this approach.

National Institutes of Health (NIH)

We recommend \$7.151 billion for **the National Institute of Allergy and Infectious Diseases**, including \$608 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.

Department of Agriculture -Food and Drug Administration

Food and Drug Administration

We recommend \$20 million to support FDA's One Health efforts to combat antibiotic resistance bacteria. This level of support is required to measure changes in 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 and begin implementation of its new plan, including strengthening the National Antimicrobial Resistance Monitoring System (NARMS) to make it consistent with One

Health principles, and issuing a final guidance on establishing duration limits to ensure that all FDA-approved veterinary indications carry duration limits needed to protect public health. This funding could also advance FDA's plan to create and implement a functional and efficient system for collecting antimicrobial use data in animals. This 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 biodefense 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.

Department of 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 FY2025. 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.

Sincerely,

Acurx Pharmaceuticals, Inc
AdvaMedDx
AIDS Action Baltimore
Aimed Alliance
Alliance for Aging Research
Alliance for Reducing Microbial Resistance (ARMoR)
Alliance for Women's Health and Prevention
AMDA - The Society for Post-Acute and Long-Term Care Medicine
American Academy of Allergy, Asthma & Immunology
American Academy of Pediatrics
American Association of Veterinary Medical Colleges
American College of Allergy, Asthma & Immunology
American College of Emergency Physicians
American Kidney Fund
American Public Health Association
American Society for Microbiology
American Society of Tropical Medicine and Hygiene
Amputee Coalition
AMR.Solutions
AN2 Therapeutics
Antibiosis Science Consulting LLC
Antibiotic Resistance Action Center, the George Washington University
Appili Therapeutics
Arixa Pharmaceuticals (Co-Founder & CEO)/Skyline Ventures
Arrepath, Inc.
Association for Professionals in Infection Control and Epidemiology
Association of Public Health Laboratories
Association of State and Territorial Health Officials
Astellas Pharma Global Development, Inc.
AUROBAC THERAPEUTICS
Bactria Pharmaceuticals, LLC
BD (Becton, Dickinson and Co.)
BEAM Alliance
Beckman Coulter Microbiology
Big Cities Health Coalition
Biotechnology Innovation Organization (BIO)
Biomeme, Inc.
bioMerieux Inc.
BioVersys AG
Blacksmith Medicines, Inc.
Bugworks Research
CancerCare

Clarametyx Biosciences
Coalition of Skin Diseases
COPD Foundation
Council of State and Territorial Epidemiologists
CUBRC, Inc.
Cystic Fibrosis Foundation
discoveric bio beta Ltd.
Donum Therapeutics
Ebright Laboratory, Waksman Institute, Rutgers University
Element Iowa City/JMI Laboratories
Elizabeth Glaser Pediatric AIDS Foundation
Emory Antibiotic Resistance Center
Equality California
Evotec
F2G Inc
Febris Therapeutics, Inc.
Five Horizons Health Services
Food Animal Concerns Trust
Foundation for Neglected Disease Research
Gerontological Society of America
Global Hygiène
Greater San Diego Biological Solutions
Harvard Medical School
HealthCare Institute of New Jersey (HINJ)
HealthHIV
Healthy Men Inc.
HealthyWomen
Hearts Consulting Group, LLC
HIV Medicine Association
Housing Works, Inc.
HSC College of Pharmacy - PreClinical Research
ICAN, International Cancer Advocacy Network
Immune Deficiency Foundation
Infectious Diseases Society of America
International Association of Providers of AIDS Care
JAV Product Realization, LLC
Jimma University
Kineticos Life Sciences
Legacy Community Health
Lupus and Allied Diseases Association, Inc.
Making-A-Difference in Infectious Diseases
Massachusetts General Hospital
McCarthy Consultants, Inc.

Melinta Therapeutics
Michigan Antibiotic Resistance Reduction Coalition
Mycoses Study Group and Education Consortium
NASTAD
National Association of Pediatric Nurse Practitioners
National Athletic Trainers' Association
National Black Nurses Association, Inc
National Coalition for LGBTQ Health
National Consumers League
National Hispanic Council on Aging
National Network of Public Health Institutes
NBCO Inc
NC Public Health Association
Novo Holdings US Inc.
NTM Info & Research
Omnix Medical
Oregon Coalition of Local Health Officials
Pediatric Infectious Diseases Society
Phare Bio
Pharmacometric Consulting
Precisio Biotix Therapeutics
Queen Biotechnologies
Qpex Biopharma
ReNewVax Ltd
Resolvix Bio
Sepsis Alliance
Sequella, Inc.
Seres Therapeutics
Shelton Professional Services
Shionogi Inc
Siemens Healthineers
Society for Healthcare Epidemiology of America
Society for Public Health Education
Society of Critical Care Medicine
Society of Infectious Diseases Pharmacists
Spina Bifida Association
Stanford University
Staurus Pharmaceutical
Stop TB USA
Stuart B Levy Center for Integrated Management of Antimicrobial Resistance at Tufts
TB Alliance
TCYCA
The Bonnell Foundation: Living with Cystic Fibrosis

The Highgate Group
The National Association of Directors of Nursing Administration (NADONA)
Treatment Action Group
Trust for America's Health
Turn Therapeutics
United Cerebral Palsy
University of Milano-Bicocca
Upstream Population Health Ltd. Co.
Vasculitis Foundation
Venatorx Pharmaceuticals
Washoe Tribal Health Center
Wellness Equity Alliance
Xiretsa, Inc.
Zavante Royalty Corporation